

Examining the Variation in Child Vaccination Status by  
Maternal Vaccination and Birthing Place

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## **Dedication**

In memory of my mother, Carmen Kaye (Fuchs) Krause (1965-2006).

For my amazing children, Tavin and River, and my always supportive husband, Brady.



## **Abstract**

Outbreaks of vaccine-preventable illnesses have occurred in recent years in pockets of children who are not up-to-date on their vaccinations, particularly among those whose parents have chosen to delay or refuse vaccinations for their children. It is essential to identify the at-risk children and the characteristics of parents who choose to delay or refuse vaccinations for their children. Numerous studies have focused on the beliefs and attitudes of parents regarding childhood vaccination, but few have focused on the association of other preventive health behaviors with childhood vaccination. Clustering of these behaviors is an important question in social epidemiology and could help in understanding underlying belief systems that influence health behaviors.

Mothers who refuse influenza vaccinations during pregnancy report similar attitudes and beliefs to those who refuse vaccinations for their children, yet few studies have investigated relationships between child vaccination and other health behaviors. Additionally, mothers who choose to deliver their babies in out-of-hospital settings, a small, but growing, population in Minnesota, also report similar attitudes and beliefs, though this research is in its infancy.

The objective of this study was to examine the variation in infant vaccination by maternal vaccination in pregnancy and maternal attitudes and beliefs using data from the Minnesota Pregnancy Risk Assessment Monitoring System and the Minnesota Immunization Information Connection. An exploratory study of the relationship between out-of-hospital birth and vaccination is also included. If relationships exist between these factors, there may be an opportunity for targeted vaccination interventions in subgroups of pregnant women or new mothers.

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## **Chapter 1: Introduction**

Vaccination is generally considered one of public health's top achievements.

While the improvement in sanitation, mostly that of clean water, has undoubtedly helped curb the spread of infectious diseases over time, vaccination has eradicated one disease, smallpox (Arita & Breman, 1979), and controlled several others, particularly polio, measles, and pertussis among children, since it became routine in the 20<sup>th</sup> century (Plotkin, Orenstein, & Offit, 2013). Beginning in the latter part of the 20<sup>th</sup> century, a variety of events occurred which stirred up parental concerns about the safety of vaccines and increased parental distrust of public health officials, including the removal of a vaccine preservative without scientific warrant, the withdrawal of a rotavirus vaccine from the market, and the addition of a vaccine to the vaccination schedule in one state without going through the traditional channels (Largent, 2012). From media coverage of anti-vaccination celebrities to parent-sponsored advertisements admonishing vaccine additives, vaccine safety frequently gets more press than vaccine efficacy (Largent, 2012). Public health officials have struggled to address parents' concerns and vaccine-hesitancy has continued to grow.

Despite the success of vaccination programs, in the United States, a growing contingent of parents is choosing to refuse some or all of the recommended childhood vaccines. Outbreaks of vaccine-preventable illnesses, such as pertussis and measles, have occurred in recent years in pockets of children who are not up-to-date on their vaccinations. Since many of these outbreaks are occurring in groups of children who have not been vaccinated, it is essential to identify new targets or methods for outreach.

While overall vaccination compliance is still high, coverage rates for some vaccines are decreasing and are well below Healthy People 2020 (HP2020) targets (Centers for Disease Control and Prevention, 2013b), which are coverage goals based on available national data, advisory committee recommendations, and consistency across national programs and policies (U.S. Department of Health and Human Services, 2015). In Minnesota, where recent spikes and outbreaks of vaccine-preventable illnesses have occurred (Gahr et al., 2014; Minnesota Department of Health, 2014c), vaccination for the full series that is recommended to occur prior to 19 months of age is below the HP2020 goal (**Table 1.** Vaccination coverage and goals for children age 19-35 months). The full series includes: 4+ diphtheria, tetanus, and acellular pertussis (DTaP) vaccinations; 3+ polio vaccinations; 1+ measles, mumps, and rubella (MMR) vaccination; a full series of Haemophilus influenzae type B (Hib) vaccinations (number of vaccinations may vary based on formulation); 3+ hepatitis B vaccinations; 1+ varicella vaccination; and 4+ pneumococcal conjugate vaccinations (PCV) (Centers for Disease Control and Prevention, 2015a).

<b>Table 1. Vaccination coverage and goals for children age 19-35 months.</b>								
	<i>DTaP</i>	<i>Polio</i>	<i>MMR</i>	<i>Hib</i>	<i>Hepatitis B</i>	<i>Varicella</i>	<i>PCV</i>	<i>Complete Series</i>
Minnesota	90.5%	94.8%	90.8%	89.7%	90.3%	89.2%	90.8%	74.1%
National	83.1%	92.7%	91.9%	82.0%	90.8%	91.2%	82.0%	70.4%
HP2020 Baseline	84.6%	93.6%	92.1%	54.8%	93.5%	90.7%	80.1%	44.3%
HP2020 Current Goals	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	80.0%
Adapted from a table created by the Minnesota Department of Health with data from the National Immunization Survey (Minnesota Department of Health, 2014b) and Healthy People 2020 (U.S. Department of Health and Human Services, 2015).								

Parents are increasingly choosing not to vaccinate their children while some are choosing to delay vaccinations (Smith et al., 2011). Much of the recent decrease in

vaccination is attributed to a now retracted and fraudulent article published in *The Lancet* in 1998, claiming a causal link between the measles, mumps, and rubella (MMR) vaccine and autism (Wakefield et al., 1998). Vaccination rates are still lagging despite the retraction of this paper, two reviews and reports by the Institute of Medicine (Institute of Medicine, 2013; National Research Council, 2004), and numerous, large, epidemiologic studies which have found no evidence for a link between vaccines or the vaccine preservative, thimerosal, and autism (DeStefano, Bhasin, Thompson, Yeargin-Allsopp, & Boyle, 2004; Hornig et al., 2008; Madsen, Hviid, Vestergaard, & et al., 2002; Price et al., 2010; Richler et al., 2006; Stehr-Green, Tull, Stellfeld, Mortenson, & Simpson, 2003; B. Taylor et al., 2002; Tozzi et al., 2009; Verstraeten et al., 2003).

The same antigens, or parts of antigens, that would otherwise cause disease are killed or weakened and used in vaccines in order to solicit an immune response from the vaccinated individual (Centers for Disease Control and Prevention, 2014c). The immune system then produces antibodies that protect the individual from these diseases without the person suffering the negative consequences of the diseases themselves (Centers for Disease Control and Prevention, 2014c). Community immunity, also known as herd immunity, is the situation where enough people in a community are protected through vaccine-induced and/or illness-induced immunity so those who are not vaccinated would be protected, since the illness would be unlikely to spread in that community (Centers for Disease Control and Prevention, 2013e). Community immunity relies upon the assumption that if immunity is conferred randomly in a population and if population mixing also occurs randomly, transmission of the disease should decline if those immune exceed a certain proportion calculated as  $1/(1-R_0)$ , where  $R_0$  is the basic reproduction

number and is different for each vaccine-preventable disease (Fine, Eames, & Heymann, 2011). Community immunity is generally relied upon to protect children who have not received certain vaccines due to age, immunocompromised children and adults, and children and adults for whom vaccination did not induce sufficient immune response.

There are some caveats to this definition of community immunity, though. The simple calculation of the proportion needed to ensure community immunity assumes population homogeneity and random mixing of the population, which are generally not valid in cities (Fox, Elveback, Scott, Gatewood, & Ackerman, 1971). More appropriate would be to consider social subgroups and mixing, seasons, number of those susceptible, and infectivity of the particular agent (Fox et al., 1971). Nonrandom vaccination in social subgroups should also be considered (Fine et al., 2011) due to the clustering of parents who choose to not vaccinate their children and especially the clustering of those children themselves where infectious agents may spread rapidly (Eames, 2009).

Unfortunately, with the resultant decrease in community immunity that comes with lower vaccination uptake, vaccine-preventable illnesses are then able to spread to vulnerable populations. In the United States in 2014, 668 cases of measles occurred in 27 states associated with 23 outbreaks, which was the highest number of cases since measles was deemed eliminated in 2000 (Centers for Disease Control and Prevention, 2015c). Pertussis, particularly lethal among infants under 3 months, is also increasing, with a provisional 28,660 cases reported in 2014, an 18% increase over the provisional numbers from 2013 (Centers for Disease Control and Prevention, 2015d).

In order to keep the incidence of vaccine-preventable illnesses from increasing further, it is important to know why parents are not vaccinating their children and, in



particular, what beliefs and attitudes parents hold that may cause them to refuse or delay vaccination of their children. Safety concerns, avoidance of medical interventions, negative personal experiences, distrust of medical personnel, and a desire for a more “natural” or alternative method have been reported across reviews (Brown et al., 2010; Mills, Jadad, Ross, & Wilson, 2005; Roberts, Dixon-Woods, Fitzpatrick, Abrams, & Jones, 2002). Most studies investigating these topics, though, have lacked the sample sizes to identify subgroups reporting certain beliefs more often than others (Gaudino & Robison, 2012) and many studies use self-report to assess child vaccination status.

Further, the focus on the beliefs themselves is a simplification of parent hesitation about vaccination. This approach gives little credit to caring parents who desire to make informed decisions in the best interests of their children, but must navigate a plethora of print and online material “contain[ing] an astounding range of authoritative-sounding claims and anecdotes, capable of worrying any parent, especially one who lacks formal medical training, has preexisting concerns about vaccines, or has a tense relationship with his or her child’s pediatrician” (Largent, 2012, p. 38). Public health officials may not be addressing the larger picture with a focus on defensive tactics and education.

While seemingly unrelated to child vaccination, an innovative study has recently shown a link between topical fluoride refusal and vaccination refusal in children (Chi, 2014). Associations between different preventive care components and characteristics which parents report impacting their decision-making processes for their children’s health care are troubling, though this suggests it may not just be about the component (e.g. fluoride) of preventive care itself. Another study has shown potential for links between maternal Pap testing and daughter’s HPV vaccine uptake (Chao, Slezak, Coleman, &

Jacobsen, 2009) and one more links vitamin K injection refusal with MMR refusal (Cassell et al., 2006). Parents who are refusing standard preventive care for their children may exhibit certain health attitudes, beliefs, and behaviors of their own that could potentially be addressed by health care providers, possibly even *before* the birth of a child.

Currently, the tetanus, diphtheria, and acellular pertussis (Tdap) vaccine and the influenza vaccine are recommended for all pregnant women (American College of Obstetricians and Gynecologists, 2013, 2014). While pregnant women are at increased risk of complications from influenza and can be protected by the influenza vaccine, prenatal influenza vaccination is also important in order to protect neonates through transplacentally acquired antibodies from the mother during pregnancy (American College of Obstetricians and Gynecologists, 2014). The Tdap vaccination of mothers during pregnancy offers similarly acquired antibodies to protect neonates from tetanus, diphtheria, and pertussis before they are able to be vaccinated (American College of Obstetricians and Gynecologists, 2013). Tdap vaccination further protects the infant beyond passively acquired antibodies by cocooning him/her, that is, ensuring immunity of those around him/her (American College of Obstetricians and Gynecologists, 2013; Murphy et al., 2008). This is especially important for the protection of infants from pertussis, as the majority of morbidity and mortality for pertussis occurs in infants under 3 months of age (Van Rie, Wendelboe, & Englund, 2005) and infants in the United States are not scheduled to have their first vaccination for pertussis, in the form of the DTaP vaccine, until 2 months of age (Centers for Disease Control and Prevention, 2015a).

Unfortunately, vaccination uptake during pregnancy is lower than optimal (U.S. Department of Health and Human Services, 2015), with similar themes of risk, safety,

and lack of trust in recommendations reported in studies examining this topic (Fisher et al., 2011). Despite these similarities, few studies have investigated relationships between choices mothers make for their own health and those made for children. One novel study found that, after a brief intervention, women who intended to vaccinate for influenza during pregnancy also intended on vaccinating their infants for influenza (Frew et al., 2013), suggesting an opportunity for child vaccination interventions may be even earlier than the pediatrician's office.

Another subset of mothers has reported strikingly similar beliefs regarding their own medical care to those beliefs reported in the literature about childhood vaccination. Mothers who choose to give birth at home have cited safety concerns and a desire to avoid medical interventions, among others, as their reasons to deliver at home instead of in a hospital (Boucher, Bennett, McFarlin, & Freeze, 2009). While there has been a *decrease* in vaccination uptake, *more* women are choosing to give birth in locations other than hospitals. There are a variety of options for women during pregnancy, labor, and delivery, from the choice of provider to the choice of birthing location and beyond. Most women in the United States currently give birth in hospitals with physicians or certified nurse-midwives as their birth attendants, but some women are choosing other locations, such as birth centers or their homes, and other care providers, such as lay midwives.

While the percentage of women choosing to deliver at home is still low, the proportion of mothers choosing out-of-hospital (OOH) birth, generally referring to births occurring in residences, birth centers, or any other non-hospital setting, has been increasing and, like many other states, there have been significant increases in OOH birth in Minnesota in recent years. The percentage of mothers having OOH births more than

doubled in Minnesota from 2004 to 2012 (MacDorman, Matthews, & Declercq, 2014). In 2012, the most recent year for which an estimate of OOH births is available for Minnesota, 68,783 births occurred (Minnesota Department of Health, n.d.-c). Of these, 849 births are estimated to have been OOH births using an estimate of 1.24% of all births (MacDorman et al., 2014).

Unfortunately, high-quality research is sparse for both the clinical outcomes and the social and behavioral characteristics of women who choose OOH birth in the United States. Women who plan to have OOH births may not be in contact with health care providers that participate in research activities, they may be less willing to participate in studies, and/or the importance of this topic has been under-recognized by epidemiologists, funding agencies, or other scientists. Demographic characteristics of women having planned home births reveal remarkable differences to mothers who deliver in hospitals in the United States. Women who plan to have home births are more likely than women having hospital births to be white, non-Hispanic, over 30 years old, married, urban, non-smokers, and highly educated (Declercq, Macdorman, Menacker, & Stotland, 2010). Most planned home births are attended by midwives, in contrast to hospital births, which are mostly attended by physicians (Declercq et al., 2010). Some women are also choosing to forego all assistance during labor and delivery, and even less is known about these unassisted, planned home births. What is known is that planned home births generally have a lower risk profile than hospital births (MacDorman et al., 2014), most home births are planned (Wax, Pinette, Cartin, & Blackstone, 2010), and that planned home birth seems to present some excess risk of neonatal mortality (Wax, Lucas, et al., 2010).

Recently, the incidence of home and other OOH birth has been increasing. In 2012, the overall percentage of OOH births in the United States was 1.36%, up from 0.86% in 2004 (MacDorman et al., 2014). Home and other OOH birth has been increasing among all racial and ethnic groups, particularly in non-Hispanic white women. The percentage of OOH births among non-Hispanic white women was 2.05% in 2012, up from 1.20% in 2004 (MacDorman et al., 2014). Two thirds of all OOH births occur at home, though births at freestanding birth centers make up 29% of OOH births (MacDorman et al., 2014).

These rates do vary by state, however, due to a variety of factors. Some states have laws licensing freestanding birth centers, which allow mothers to deliver in a setting other than a hospital, but with licensed staff who have experience with low-risk births (American Association of Birth Centers, 2013). Birth center births and birth centers themselves are increasing, as they may present as an appealing option for women who desire a home-like setting or as a more cost-effective option. Delivering in a birth center may be more cost effective than having an uncomplicated vaginal birth in a hospital (American Association of Birth Centers, 2013) and, unlike planned home births which have higher neonatal mortality, appears to have a similar neonatal mortality risk to planned hospital births (O'Hara et al., 2013; Stapleton, Osborne, & Illuzzi, 2013). Minnesota started allowing the licensing of freestanding birth centers in 2011 (Office of the Revisor of Statutes - State of Minnesota, 2014c), though data is not yet published on the impact on OOH births this has had, it is expected that the number of mothers who choose birth centers will continue to increase (American Association of Birth Centers, 2013).

Since there are similar beliefs among women who choose OOH birth and among parents who choose to refuse or delay vaccinations, it is possible that these two populations are related or overlapping and have beliefs or concerns that are not being adequately addressed by health care providers. Even more, nonrandom vaccination and/or clusters of like-minded people who are choosing not to vaccinate could account for the rapid spread of vaccine-preventable illnesses in some populations where community immunity breaks down (Eames, 2009; Fine et al., 2011). If there is a difference in vaccination in children of women who deliver OOH compared to those who deliver in hospitals and/or if there is a difference between the attitudes and beliefs of mothers who have OOH births and those who have hospital births, these differences can then be addressed through public health interventions *prenatally* in order to increase vaccination and, therefore, reduce the incidence of vaccine-preventable illnesses. One study investigating vaccine beliefs of postpartum mothers found a need for prenatal interventions due to the frequency of reported vaccine concerns and low knowledge about vaccines, reporting that most did not receive information about childhood vaccinations during pregnancy (Wu et al., 2008). A prenatal intervention may be especially important since a new study reports that pediatricians are inadequately prepared to talk about vaccine safety, a common concern reported by parents, with the families in their practices (Williams & Swan, 2014) and another reports that vaccine-hesitant mothers would like vaccine information prior to their children's first vaccination visits (Vannice et al., 2011).

The objective of this study is to examine the variation in infant vaccination by maternal vaccination in pregnancy, maternal attitudes and beliefs, and birthing place. If relationships exist between these factors, there may be an opportunity for targeted

vaccination interventions in subgroups of pregnant women or new mothers in Minnesota. Minnesota is an ideal place to complete this study and, with its sharply increasing OOH birth rate, low vaccination series completion rates, and its vast public health infrastructure, data already collected can be used to investigate this question.

In order to address the objective of this study, an analysis of existing surveillance data was conducted by merging data from the Minnesota Pregnancy Risk Assessment Monitoring System (MN PRAMS), which surveys mothers on a variety of topics, including vaccination beliefs and behaviors, and infant vaccination records from the Minnesota Immunization Information Connection (MIIC) database. Birthing location was ascertained from MN PRAMS, which is linked to vital statistics data. Analyses included Pearson's chi-squared tests, Fisher's exact tests (when appropriate), and logistic regression models. This study examines the following aims and hypotheses.

**Aim 1.** Examine whether child vaccination status differs by maternal influenza vaccination status and maternal beliefs regarding the influenza vaccine.

***Hypothesis 1.*** There will be a difference in up-to-date vaccination status in children of mothers who received the influenza vaccine during pregnancy and those who did not.

***Hypothesis 2.*** Among those who did not have the influenza vaccine during pregnancy, there will be a difference in up-to-date vaccination status in the children of mothers who indicated concern about side effects of the influenza vaccine compared to those who did not.

**Hypothesis 3.** There will be a difference in up-to-date vaccination status of individual vaccines in children of mothers who received the influenza vaccine during pregnancy and those who did not.

**Aim 2 - Exploratory.** Examine whether child vaccination status and maternal influenza vaccination differ by birthing place.

**Hypothesis 1 - Exploratory.** There will be a difference in up-to-date vaccination status between the children of mothers who had OOH births and those who did not have OOH births.

**Hypothesis 2 - Exploratory.** There will be a difference in OOH births between mothers who had the influenza vaccine during pregnancy and those who did not.

Vaccine refusal has been increasing, as have vaccine-preventable infectious diseases in populations who are unvaccinated. So far, public health efforts have been unable to successfully address these issues and outbreaks are continuing. Since many of the same ideals reported by women who choose not to vaccinate their children are also reported by women who refuse influenza vaccination during pregnancy and women who have OOH birth, it is possible that these populations overlap, but this has not been previously investigated. Additionally, this is the first time these datasets have been linked. Linking these datasets allows for temporality to suggest whether there may be some causation of the lack of infant vaccination by previous maternal attitudes, beliefs, and behaviors. Linking these datasets also allows for a new use of existing resources. Public health data is often laborious and expensive to collect and time and personnel limitations often restrict state health agencies from conducting predictive analyses. As of April 2015, there are no published articles examining the relationship between or impact of maternal



influenza vaccination or birthing location on child vaccination series completion in developed countries. If a link exists, this could reveal an opportunity for *prenatal* vaccination interventions in some sub-populations that could be vulnerable to vaccine-preventable illnesses.

This study contributes to the literature on predictors of early childhood vaccination by examining the association with maternal health behaviors and beliefs. While previous research has focused on proximal factors as predictors of vaccine uptake, this study focuses on maternal beliefs and preventive health choices that occur, sometimes months, prior to recommended childhood vaccinations. Early childhood vaccine series completion is currently below ideal levels and vaccine-preventable illnesses continue to occur. Results of this study may identify opportunities for future research into maternal behaviors as predictors of early childhood vaccination and an opportunity for targeted prenatal early childhood vaccination interventions.

## Chapter 2: Previous Research

### Introduction to the Review

In order to develop a complete picture of the current understanding of infant vaccination, maternal vaccination, and birthing place, a review of the literature was conducted. While there is a plentiful research base regarding maternal attitudes and beliefs about vaccination, few studies examine attitudes and beliefs regarding place of birth, particularly planned OOH birth, and few studies examine maternal vaccination and its relationship with infant vaccination. Though the present study focuses on health behaviors within the United States, and more specifically, in Minnesota, it is important to discuss the high quality literature reviews and noteworthy studies from other developed nations. Findings from these reviews and key clinical points are discussed.

### Review of the Literature

Each topic in the review of the literature used similar search terms. **Table 2** lists the review terms by topic area and will be referred to in the sections that follow.

<b><i>Table 2. Search terms by topic area.</i></b>				
<i>Parent Terms</i>	<i>Vaccination Terms</i>	<i>Belief Terms</i>	<i>Birth Terms</i>	<i>Pregnancy Terms</i>
parent mother maternal	immuni* vaccin* inoculat*	belief attit* percept* opinion* expectat* reason*	homebirth home birth childbirth at home birth at home out of hospital birth deliv* at home unassisted childbirth birth center alternative childbirth	pregnant pregnancy

**Vaccination attitudes, beliefs, and behavior.** A search of the literature was performed for English language articles through April 2015 using PubMed, Ovid MEDLINE®, and PsycInfo. The reference sections of included articles were also searched for additional relevant articles. Search terms included the parent terms,

vaccination terms, and belief terms from **Table 2**. Those reported on below met the following criteria: (1) addressed/examined self-reported parental beliefs and/or attitudes with regard to vaccinations that are currently recommended by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP) (Centers for Disease Control and Prevention, 2015a); (2) reported original data; (3) written in the English language; (4) published in a peer-reviewed journal; (5) published after 1998; (6) conducted in the United States; (7) focused on infants and preschool-aged children; and (8) report on the attitudes, beliefs, and perceptions of parents who delay or refuse vaccinations for their children. Editorials were excluded.

A total of 1,464 titles and abstracts were reviewed (526 from PubMed and 938 from Ovid MEDLINE® and PsycInfo), including 72 review articles. Citation searching was also performed, but did not result in any additional articles. A total of 23 articles and 4 reviews examined these topics.

There have been several systematic reviews of studies reporting parents' attitudes and beliefs regarding vaccination. None of these reviews and none of the studies included in them have focused on mothers who chose to have OOH births. Systematic reviews of studies reporting parents' attitudes and beliefs regarding vaccination have revealed consistent themes. Safety concerns, avoidance of medical interventions, negative personal experiences, distrust of medical personnel, negative opinions about vaccinations, and a desire for a more "natural" or alternative method have been reported across reviews (Falagas & Zarkadoulia, 2008; Mills et al., 2005; Sturm, Mays, & Zimet, 2005; Wallace et al., 2014). Four reviews were excluded due to being primarily about human

papillomavirus (HPV) vaccination or due to the focus on attitudes and beliefs of parents in other countries (Brewer & Fazekas, 2007; Brown et al., 2010; Grimes, Benjamins, & Williams, 2009; Zimet, 2005), though these reviews revealed similar themes, with the exception of some specific concerns related to the HPV vaccine. One recent international review suggests that vaccine concerns vary over place and time and also vary by type of vaccine (Larson, Jarrett, Eckersberger, Smith, & Paterson, 2014).

The individual studies identified in this search, the majority of which were encompassed in the reviews, identified the same attitudes and beliefs as those concluded as themes in the reviews. Some articles were excluded since they examined beliefs about vaccinations in school-aged children or adolescents, which is not relevant to the population of interest in this study.

In a study examining beliefs of parents who delay or refuse vaccinations, parents reported H1N1 influenza, seasonal influenza, and varicella as the most likely vaccinations they would refuse; MMR, varicella, and seasonal influenza as the most likely vaccinations they would delay; and MMR, DTaP, and PCV as the most likely vaccinations they would spread over a longer period of time (Dempsey et al., 2011). Many of the parents who chose to refuse or delay vaccinations in this population believed that delaying vaccinations or using an alternative schedule would be safer than giving them at the times recommended by vaccination experts (Dempsey et al., 2011). Another study investigated beliefs separately by vaccine and found different reasons for refusal of different vaccines. MMR vaccine refusers were most likely to report reading about problems, risk of side effects, and a perceived lack of research on the MMR vaccine while varicella vaccine refusers were most likely to report that they would rather have

their child get the illness, a perceived lack of research, and a belief that the vaccine is ineffective (Freed, Clark, Butchart, Singer, & Davis, 2010). This study also investigated reasons for refusal of the meningococcal conjugate vaccine and the HPV vaccine, though these vaccines are not given to children under 36 months of age, so the results are less relevant to the population in the proposed study.

One study examining beliefs of parents before and after an influenza season with high media coverage found that parents who did not vaccinate their children for influenza reported barriers to vaccination, concerns about side effects, perceptions of low susceptibility to influenza for their child, and lack of perceived benefit (Daley et al., 2006). In the same study population, older age of the child and public or no insurance were negatively associated with influenza vaccination (Daley et al., 2007).

Relationships with complementary and alternative medicine (CAM) providers who were against vaccination were implicated in two studies of mothers who chose not to vaccinate or to take vaccine exemptions for their children, along with typically reported factors like fear of side effects and lack of trust (Benin, Wisler-Scher, Colson, Shapiro, & Holmboe, 2006; Gaudino & Robison, 2012).

The remaining individual studies largely identified the same reasons for refusing or delaying vaccinations as those identified in reviews, such as safety and side effects, lack of trust, perceptions of low susceptibility, lack of perceived benefit, avoidance of interventions, whether they believe their health care provider recommends the vaccine of interest, previous negative experiences, and general negative opinions about vaccines (Gilkey, McRee, & Brewer, 2013; Gnanasekaran et al., 2006; Gust, Brown, et al., 2005; Gust, Kennedy, et al., 2005; Healy, Montesinos, & Middleman, 2014; Humiston, Lerner,

Hepworth, Blythe, & Goepp, 2005; Keane et al., 2005; Kennedy, Brown, & Gust, 2005; Lavail & Kennedy, 2013; Lin, Nowalk, et al., 2006; Lin, Zimmerman, et al., 2006; Luthy, Beckstrand, & Callister, 2010; Nowalk et al., 2005; Opel et al., 2013; Shui, Weintraub, & Gust, 2006; Stockwell, Irigoyen, Martinez, & Findley, 2011; J. Taylor et al., 2002).

**OOH birth attitudes and beliefs.** A search was conducted in order to identify any other relevant articles which report beliefs of mothers who choose to deliver at home. The search query included the belief terms and the birth terms from **Table 2**.

PubMed revealed 619 results while Ovid MEDLINE® and PsycInfo revealed 357 results. The relevant few are discussed below. Citation searching brought the total to 8 articles that discuss beliefs of mothers who chose to have OOH births in the United States. While the idea that women who choose OOH births may have different beliefs than women who choose to have hospital births has been studied for many years, little is available in the form of research into why women may be choosing these options more frequently. A study in 1985 reported that women choosing to have home births emphasized control and perception of risk in the hospital as their reasons for choosing home birth (Schiff & Laferla, 1985). In 1986, one study reported that women who chose to have planned OOH births reported midwifery, ability to have one's family present, being part of the decision-making process, and faith in the birth process as their reasons for choosing OOH birth (Schneider, 1986). One descriptive study on the beliefs of women in the United States who chose home birth found that the most common reasons given by women who chose home birth were safety concerns, avoidance of medical interventions, previous negative hospital experiences, more control, and a comfortable and familiar environment (Boucher et al., 2009).

The following themes emerged in one focus group study of mothers who delivered at home after a previous hospital birth: desired choices and empowerment, did not want interventions, feelings of disrespect and dismissal in previous hospital births, comfortable environment, and feelings of connection with self, provider, and others (Bernhard, Zielinski, Ackerson, & English, 2014). Similar themes, such as trust, connection, fewer interventions, empowerment, and comfort, were found in one study reported across two articles using semi-structured interviews with mothers who chose to deliver at home (Cheyney, 2008, 2011). A novel study investigating attitudes and beliefs of African American women who chose to have home births also found control, avoidance of interventions, and comfort to be the most frequently reported reasons for choosing home birth (Farrish & Robertson, 2012). A recent prospective study found that mothers who intended on giving birth at home chose that option for safety, control, and avoidance of medical interventions (Regan & McElroy, 2013). A qualitative study identified safety as the major theme in the reasons women choose home birth, encompassing a variety of factors such as avoidance of interventions, personal relationships, comfort, and having a back-up plan (Lothian, 2013).

Attitudes and beliefs of those choosing to have birth center births are reported on even less frequently. A fairly old study of women who chose birth centers reported similar themes to those choosing home birth: comfort, preference for midwifery, fewer interventions, and safety (Klee, 1986).

Due to the lack of articles published examining attitudes and beliefs of mothers who choose OOH birth in the United States, a discussion of a few key articles and a review in other developed countries follows. These findings may not be generalizable to

women in the United States since there are large differences in the social, cultural, economic, and health systems. One international review discussed the following themes: choice and preference for fewer interventions, preference for midwifery, safety, and autonomy (Hadjigeorgiou, Kouta, Papastavrou, Papadopoulos, & Mårtensson, 2012). A semi-structured interview study in Australia with women who chose to deliver at home unassisted found the primary concern was safety (Jackson, Dahlen, & Schmied, 2012). A slightly older, but larger, study in Canada found support, empowerment, avoidance of interventions, comfort, control, and preferences for midwifery as emerging themes (Janssen, Henderson, & Vedam, 2009). A review of studies of reasons for home birth among multiparous women found the following themes: control, safety, and experiential reasons (Ashley & Weaver, 2012).

It has long been known that women who desire a more “natural” birth experience choose midwives over obstetricians for care (Howell-White, 1997), but it is important to mention that choice of birth attendant is not discussed separately here. While the preference for care by a midwife is a frequent theme reported by mothers who choose OOH birth, in the United States, it is possible and common to have a midwife and still choose to deliver at a hospital. In fact, the vast majority of births attended by midwives occur in hospitals (Martin, Hamilton, Osterman, Curtin, & Mathews, 2013). Mothers who choose to have OOH births are more likely to choose their birthing place first and then choose their provider, whereas mothers who choose to deliver in a hospital are more likely to choose their provider first (Hodnett, 1989). Links solely between preference for care by a midwife and infant vaccination have not been investigated.



**OOH birth and vaccination.** There were few search results in PubMed or PsycInfo when OOH birth key words were added to the vaccination query. The query included the birth terms and the vaccination terms from **Table 2**. There were 153 results in PubMed and 52 results in Ovid MEDLINE® and PsycInfo. When the belief terms from **Table 2** were added to this query, there were 33 results in PubMed and 15 results in Ovid MEDLINE® and PsycInfo.

Only one article was found which assesses the relationship between OOH birth and vaccination in the United States, which was a result in both queries. “Alternative childbirthing” was found, after adjustment, to be an independent risk factor for parents who chose to claim personal belief exemptions from school vaccination requirements in Oregon (Gaudino & Robison, 2012). However, this study only assesses those taking personal belief exemptions for their children and does not focus on children who are not yet school-aged. This study does not investigate any relationships between maternal vaccination and child vaccination, maternal vaccination and exemptions, or vaccine-related beliefs and OOH birth. It does link chiropractic care of the youngest school-aged child to exemption, the only non-vaccination health care choice assessed which was an independent predictor after adjustment (Gaudino & Robison, 2012). One study conducted in Canada found an association between vitamin K refusal and OOH birth and an association between vitamin K refusal and lack of immunization (Sahni, Lai, & MacDonald, 2014).

**Maternal vaccination during pregnancy.** A search was conducted in order to identify any relevant articles that report beliefs of mothers who are offered vaccinations during pregnancy. The search query included the belief terms, the pregnancy terms, and

the vaccination terms from **Table 2**. PubMed revealed 552 results while Ovid MEDLINE® and PsycInfo revealed 678 results. The articles meeting inclusion criteria and one review are discussed below.

Currently, it is recommended that women be vaccinated with the Tdap and influenza vaccines during pregnancy (American College of Obstetricians and Gynecologists, 2010, 2013). Several studies have examined the attitudes and beliefs of mothers regarding the influenza vaccine during pregnancy. Common themes throughout the studies emerged, such as safety (mother and fetus), low perception of risk of influenza, a lack of trust in influenza vaccine guidelines, and a lack of perceived benefit (Ahluwalia et al., 2010; Ahluwalia, Singleton, Jamieson, Rasmussen, & Harrison, 2011; Chamberlain et al., 2015; Drees et al., 2012, 2013; Eppes et al., 2013; Fisher et al., 2011; Gorman, Brewer, Wang, & Chambers, 2012; M. L. Henninger et al., 2015; M. Henninger, Naleway, Crane, Donahue, & Irving, 2013; Lynch et al., 2012; Marsh, Malik, Shapiro, Omer, & Frew, 2013; Meharry, Colson, Grizas, Stiller, & Vázquez, 2013; Moniz, Vitek, Akers, Meyn, & Beigi, 2010; Panda, Stiller, & Panda, 2011). One review with studies primarily from the United States echoes these themes of safety, trust, and low perceptions of risk of influenza (Yuen & Tarrant, 2014).

H1N1 influenza vaccine has been researched separately. One study of H1N1 influenza vaccine found that worry about acquiring the disease was a stronger predictor of intention to vaccinate than perceptions of risk or safety (Tucker Edmonds, Coleman, Armstrong, & Shea, 2011) while another found perceived barriers, such as side effects, and perceived severity of infection to be independent predictors of vaccination (Fridman

et al., 2011). Others found benefits to the baby and safety to be important (Goldfarb, Panda, Wylie, & Riley, 2011; Kharbanda et al., 2011; Steelfisher et al., 2011).

Recall of provider recommendation remains another important factor in influenza vaccination during pregnancy (Ahluwalia et al., 2010; Drees et al., 2012; Goldfarb et al., 2011; Gorman et al., 2012; Kharbanda et al., 2011; Panda et al., 2011; Silverman & Greif, 2001; Steelfisher et al., 2011; Vitek et al., 2011). Another study of postpartum women found provider recommendation to be an important motivator for both influenza and pertussis vaccination during pregnancy (Beel, Rensch, Montesinos, Mayes, & Healy, 2013). No studies were found which focus specifically on vaccination practices and recommendations for providers who primarily attend OOH births.

Few studies examine the effects of maternal vaccination on the vaccination status of children. Most of the studies that do examine these effects are regarding the HPV vaccine. The assumption cannot be made that any associations found with maternal HPV vaccination and child HPV vaccination also transfer to infant or early childhood vaccination since the HPV vaccine is given to older children and objections to the HPV vaccine are frequently regarding misconceptions about the potential for promiscuity (Grimes et al., 2009; Zimet, 2005).

One study examined maternal intention to vaccinate for influenza during pregnancy and found an association between this and intent to vaccinate the infant for influenza (Frew et al., 2013), though this was a novel study of an intervention and did not measure actual vaccination status.

### **Summary of Previous Research**

Previous research differs in breadth and depth by topic area. Beliefs and attitudes reported regarding child vaccination, maternal vaccination during pregnancy, and birthing place fall into themes around safety, avoidance of interventions, trust, comfort, and perceptions of benefits. While the literature around maternal attitudes and beliefs regarding vaccination of their children is extensive, there is little about how maternal vaccination during pregnancy and OOH birth may predict childhood vaccination. Even more, there are no published articles investigating a link between childhood vaccination, maternal vaccination, maternal attitudes and beliefs, and OOH birth.

Historically, the research into predictors of child vaccination has centered on variables proximal to the time of vaccination or about the vaccinations themselves, yet interventions targeting these variables have not been effective. New avenues must be explored, especially in light of recent outbreaks of vaccine-preventable illnesses in children who are not up to date on their vaccinations. Research in other areas of health has shown that preventive health beliefs develop early in life (Lau, Quadrel, & Hartman, 1990). If some mothers already have an idea of where they would like to give birth prior to the selection of their prenatal health care provider (Hodnett, 1989), might they already have a belief system about vaccines or preventive care in general long before their children need vaccinations? Since vaccination programs targeting parental beliefs have had little success, identifying relationships between maternal preventive health beliefs and behaviors and child vaccination may spur innovation.

The objective of this study was to determine whether there is an association between maternal preventive health choices and beliefs that occur prior to the first anticipated child vaccination. This is the first study that examines prenatal influenza

vaccination as a predictor for both early childhood single and full series vaccine completion, the first study that examines the relationship between prenatal influenza vaccination and birthing place, and the first study that examines the relationship between birthing place and early childhood vaccine series completion. This study contributes evidence concerning associations between mothers' own health choices and those they make for their children.

## Chapter 3: Research Design & Methods

### Overview

Relying on existing data, an investigation into the relationships between maternal vaccination, early childhood vaccination, birthing location, and the beliefs and attitudes of mothers was conducted.

### Study Design

To address the aims of this study, an analysis of a dataset composed of two existing merged surveillance datasets was conducted. A total of 4,111 mothers who gave birth in the years 2009-2011 were identified through their participation in the Minnesota Pregnancy Risk Assessment Monitoring System (MN PRAMS). Corresponding Minnesota Immunization Information Connection (MIIC) records were identified for the children born to the mothers who participated in MN PRAMS in this date range.

**Data collection.** The Minnesota Department of Health (MDH) collected both the MN PRAMS and the MIIC data. MN PRAMS is a health surveillance project between MDH and the Centers for Disease Control and Prevention. MN PRAMS randomly selects approximately 200 mothers each month from the Minnesota Vital Statistics file of mothers who gave birth to live infants in Minnesota and mails them an introductory letter and survey 2-6 months after delivery (Minnesota Department of Health, n.d.-a). Mothers must also be Minnesota residents. Some groups of women are oversampled to “ensure adequate data” for higher risk groups (Centers for Disease Control and Prevention, 2013a). In Minnesota, black mothers who were born in the United States and American Indian mothers are oversampled due to a history of poorer birth outcomes among these groups (Minnesota Department of Health, n.d.-a).

The mothers are mailed a survey (see **Appendix A**) with return information, though some surveys are completed over the telephone (Minnesota Department of Health, n.d.-b). The detailed data collection protocol is as follows and is based on the Tailored Design Method (Dillman, 2000):

- 1) Pre-letter prior to survey arrival;
- 2) Initial questionnaire packet 3-7 days after preletter arrival;
- 3) “Tickler” thank you and reminder 7-10 days after initial packet;
- 4) Second questionnaire packet 7-14 days after tickler for those who have not yet responded;
- 5) Third questionnaire packet 7-14 days after second packet for those who have not yet responded; and
- 6) Telephone follow-up 7-14 days after third packet for those who have not yet responded, with up to 15 call attempts (Centers for Disease Control and Prevention, 2013a).

MN PRAMS has a complex sampling design, which requires weighting in order to estimate population-level means and proportions. As previously mentioned, some groups are oversampled, some groups have higher non-response rates than others, and attention is paid to the potential for omitted records due to late processing which may require additional weighting (Centers for Disease Control and Prevention, 2013a). All of these factors are combined per entry in order to create a weight that is representative of the total number of women that respondent is meant to represent. These weights were calculated per MDH protocol with variables provided with the dataset from MDH and were taken into account in the analyses. The final sample including weights gives a

representative sample of all Minnesotan women who had a live birth in Minnesota for the included years (Minnesota Department of Health, n.d.-a).

While using weights is not supported by some methodologists (Rothman, Gallacher, & Hatch, 2013), they are important when the goal is to generalize results to the population level and produce appropriate standard error estimates, as is the goal for research using MN PRAMS data (Minnesota Department of Health, n.d.-a). Rothman et al. (2013) argued that representativeness does not itself lead to scientific inference; that is, scientific inference is not enhanced by representative sampling and the average effects reported in studies using survey weights may not be applicable to each subgroup. Rothman et al. (2013) go on to explain that an understanding of nature and of the mechanisms involved can make for proper generalization rather than simply the representativeness of the sample and weighting, which instead allows for appropriate statistical inference. Using weights here with this representative sample allows for the cautious estimation of the average risks, risk differences, and standard error estimates in Minnesotan mothers and children born from 2009-2011. While there may be differences within subgroups, they are not captured here since average measures are reported. Any associations found between these factors are not likely to be causal, but merely represent the statistical relationships between these factors in the population based upon the specified models.

The MN PRAMS survey includes required core and standard questions on the following topics: maternal attitudes and feelings about the most recent pregnancy, prenatal care, alcohol and tobacco consumption, physical abuse, pregnancy-related morbidity, infant health, contraceptives, and mother's health knowledge (Centers for



Disease Control and Prevention, 2012). Also included are demographic questions and any approved supplemental questions the state includes in a given year, which may change over time depending on any salient issues (Centers for Disease Control and Prevention, 2012).

MIIC is a federally-funded state-level vaccination registry that works with providers to update vaccination records for children and adults throughout the state of Minnesota (Minnesota Department of Health, 2009). Vaccination records for all Minnesotan resident children and adults are contained in the system if they have participating providers. MIIC allows health care providers, public health agencies, and schools to locate vaccination records for patients or students and allows participants to get copies of their own or their children's records when requested (Minnesota Department of Health, 2009). Though participation is voluntary, the vast majority (85-90%) of primary care providers submit information to MIIC on a regular basis (Minnesota Department of Health, 2014a). There is a 30-day window in which vaccinations should be entered into MIIC (Minnesota Department of Health, 2014a), but over 70% of all vaccinations are entered within 7 days (Centers for Disease Control and Prevention, 2014a).

There are some limitations with MIIC data. While North Dakota and Wisconsin currently participate in data sharing with Minnesota, enabling MIIC to register vaccination information for Minnesotan children who have been vaccinated in these states, the same is not true for Iowa or South Dakota, so some border county children may appear to be missing vaccinations (Minnesota Department of Health, 2014a). Ninety-three percent of Minnesotan children aged 24 months through 35 months have at

least 2 non-influenza vaccination records in the MIIC system as of January 2015 (Minnesota Department of Health, 2015). The remaining 7% represents children whose parents have opted out of or delayed vaccinations, children who have medical exemptions, children whose providers do not participate in MIIC, and children who live in border areas that do not participate in data sharing.

***Data merge.*** MN PRAMS and MIIC datasets are both connected to birth certificate data. Matching MIIC records for the children of the mothers who appeared in the 2009-2011 MN PRAMS data were identified by MIIC personnel by matching on birth certificate number, ensuring that the mothers who completed the MN PRAMS survey were matched with the appropriate child for the pregnancy on which they reported in MN PRAMS. The datasets were de-identified by MDH personnel and given generic identification numbers prior to access by the principal investigator. Datasets were merged together by the principal investigator on the generic identification number.

***Data cleaning and editing.*** MIIC does extensive follow-up on children who do not have vaccination records in the MIIC system. Children who died were excluded from the analyses. There were no children in this sample who had medical exemptions for any vaccines. Missing data MN PRAMS was very low, with, for example, only 1.4% (weighted) missing on the indicator for whether or not the mother had an influenza vaccination during pregnancy. The dataset was thoroughly checked for values outside the possible range for each variable and was checked for impossible values. Variables were edited as needed to produce indicator variables as described in the analysis plan.

***Subject characteristics.*** Subjects included 4,111 MN PRAMS respondents from 2009-2011 who had live births and their children. In order to protect the children from

being identifiable, only months of age at the time of the data export was available to the principal investigator, including months of age at the time of each vaccination. Maternal characteristics reflect demographic characteristics of Minnesotan resident mothers who had a live birth by year of survey due to stratified random sampling and complex weighting.

### **Analysis Overview**

All analyses were completed using the svy suite of commands in Stata SE Version 13.0 (StataCorp, 2013) in order to take into account the weights required in the analysis of complex survey data. Descriptive analyses included Chi-squared tests, Fisher's exact tests, and t-tests. Logistic regression was used to estimate log odds (not reported) for childhood vaccination status and OOH birth, while margins post-estimation commands in Stata were used to obtain predicted probabilities and risk differences. Unweighted analyses were conducted, but not presented, in order to ensure that the findings were qualitatively consistent.

Both descriptive and predictive methods have their downfalls. Tabular methods are easily interpretable, however, they lack the ability to represent more complicated relationships between variables since we cannot stratify beyond one or two potential variables without it becoming intractable. The tabular method also assumes homogeneity within the dichotomous groups, though this is also the case in regression if, for example, categorizing continuous data. Tabular representation does not account for any confounding nor does it allow the easily interpretable modeling of a continuous exposure.

Regression allows us to examine more complicated relationships between variables as long as we make certain assumptions. The first assumption is that the people

in the groups that are being compared are exchangeable. This assumption is almost certainly violated due to self-selection. Regression itself is an attempt to get *conditional* exchangeability between groups. The second assumption here is positivity, that everyone has a positive chance of being exposed. This assumption is not violated since anyone in this population may have any of the exposures. In logistic regression, other assumptions include dichotomous outcome variables and independence of observations. The outcomes that were used in these analyses were all dichotomous and there was no reason to expect correlation between observations. It is possible, but unlikely, that some mothers were randomly sampled more than once during this three-year period if they had more than one birth in this time frame, but, due to privacy concerns, this information was not available to the investigator.

The margins post-estimation commands in Stata after running logistic regression models were used in order to estimate risk and risk differences. While many studies on vaccination use logistic regression to estimate odds and odds ratios and then report these odds ratios, a limitation of logistic regression is the reduced interpretability of an odds ratio. While the odds ratio would provide for comparability with previous studies of predictors of vaccination coverage that use odds ratios in their reporting, this is undesirable since the lack of vaccine series completion is a common outcome and the odds ratio would not approximate the risk ratio (Zhang & Yu, 1998). A risk difference is an easily interpretable additive measure that can be used for guiding interventions and policy. Poisson regression was rejected since investigating vaccination counts is not informative in a population where the children may be receiving different combinations and formulations of vaccines. For example, a child may receive either 3 or 4 Hib vaccines

depending on the type of Hib vaccine used (Centers for Disease Control and Prevention, 2015a).

**Measures.** The definitions of each variable of interest and their coding schemes are detailed below. The MN PRAMS survey is included as the **Appendix A**, while the seasonal influenza supplement is included as **Appendix B**.

***Child vaccination status.*** MIIC and the National Immunization Survey (NIS) report vaccination statistics on different age ranges of children. MIIC assesses children from 24-35 months, whereas NIS assesses children from 19-35 months (Minnesota Department of Health, 2014a). This study used NIS variable definitions in order to be comparable to national estimates and HP2020 objectives; however, all children included in this analysis were 3 years of age or older.

Child vaccination status was ascertained from MIIC records. In order to provide the most useful information for overall vaccination compliance, a dichotomous indicator variable was created, with 1 representing up-to-date vaccination status, that is, children who have completed prior to 36 months of age the entire series of vaccinations that are recommended to occur by 19 months of age (4+ DTaP, 3+ polio, 1+ MMR, full series of Haemophilus influenzae type B, 3+ hepatitis B, 1+ varicella, and 4+ PCV) (Centers for Disease Control and Prevention, 2015a), and 0 representing children who have not completed the series. Children who were over 35 months of age were assessed according to whether or not their vaccination series was complete prior to 36 months of age. This outcome aligns with HP2020's objective IID-8 in the Immunization & Infectious Diseases topic area, to increase the percentage of children aged 19-35 months who receive the entire series (U.S. Department of Health and Human Services, 2015). MIIC

vaccine records indicated whether or not each particular vaccine record was valid based on recommended schedules, including spacing of vaccines and age of child at vaccination. Invalid vaccine records did not count toward vaccine series completion.

***Birth location.*** Birth location was ascertained from MN PRAMS data. MN PRAMS has been matched with birth certificate data, which includes birth location. A dichotomous indicator variable was created, with 0 representing hospital birth and 1 representing OOH birth. OOH birth was defined as births occurring in a home or birthing center. No births occurred in birthing centers in this sample. Birth location is also available through the MN PRAMS survey, though the location given on the birth certificate is not susceptible to issues with self-report, hence the decision to use that reported on the birth certificate. In this sample, all OOH births occurred in residences, typically referred to as home births.

***Maternal influenza vaccination history.*** Maternal influenza vaccination history was assessed per the MN PRAMS survey (see **Appendix A**) question (Centers for Disease Control and Prevention, 2009), “Did you get a flu vaccination during *your most recent* pregnancy?” A dichotomous indicator variable was recoded to 1 for a “Yes” response and 0 for a “No” response. This response option pertains to any influenza vaccine.

***Maternal beliefs.*** Maternal beliefs were assessed by whether or not those who had not received the seasonal influenza vaccination during pregnancy indicated concern in the MN PRAMS survey (see **Appendix B**) about maternal side effects or fetal side effects as reasons for not receiving the vaccine. Dichotomous indicator variables were created for

concern about maternal side effects (one variable) and fetal side effects (one variable), with 1 for a “Yes” response and 0 for a “No” response.

***Covariates.*** Prior to covariate adjustment, stratification on each demographic covariate occurred in order to evaluate the possibility of effect modification. MN PRAMS survey (see **Appendix A**) responses were used. The following covariates, due to a substantial history of associations with maternal and child health outcomes were investigated for effect modification and confounding in all logistic regression models:

1) *Maternal race/ethnicity.* Maternal race and ethnicity variables were provided separately by MN PRAMS and recoded into the following categories: white/non-Hispanic, black/non-Hispanic, Hispanic, and other non-Hispanic. Indicator variables were created for each category. The reference level was white/non-Hispanic.

2) *Maternal insurance type.* This variable was created based on MN PRAMS responses with the following categorical responses for insurance type during pregnancy: no insurance, Medicaid, private, and other. Indicator variables were created for each response option. Private insurance was the reference level.

3) *Maternal age.* Continuous age was provided by MN PRAMS and was recoded into the following categories: <18 years, 18-24 years, 25-29 years, 30-44 years, and 45+ years. It is possible that there was residual confounding due to the categorization of age. Indicator variables were created for each category. The 25-29 year old age group was the reference level.

4) *Maternal education.* This variable was provided by MN PRAMS with the following categorical responses: <high school, high school, >high school. It is

possible that there was residual confounding due to education being a categorical variable. Indicator variables were created for each response option. High school education was the reference level.

5) *Maternal income (household)*. This variable was provided by MN PRAMS with the following categorical responses: <\$10,000, \$10,000-\$24,999, \$25,000-\$49,999, and >\$50,000. It is possible that there was residual confounding due to income being a categorical variable. Indicator variables were created for each response option. Income was not included in final models due to collinearity with maternal insurance type.

6) *Parity*. This variable was provided by MN PRAMS with the following dichotomous responses: 0 live births and 1+ live births. No previous live birth was the reference level.

7) *Maternal marital status at time of birth*. This variable was provided by MN PRAMS with the following dichotomous responses: married and other. The reference level was the “other” group.

### **Analyses by Hypothesis**

Below are the detailed analysis methods by aim and hypothesis. All analyses were preceded by the appropriate survey methods settings in Stata SE version 13.1 (StataCorp, 2013) using the weights provided with the MN PRAMS dataset, in order to ensure that Taylor linearization was used to calculate appropriate standard error estimates. Statistical significance was assessed at the standard  $\alpha=0.05$  level. Aim 2 is considered exploratory due to the small sample size available for the OOH birth group.



**Aim 1. Hypothesis 1.** There will be a difference in up-to-date vaccination status in children of mothers who received the influenza vaccine during pregnancy and those who did not.

**Descriptive analysis.** Child vaccine series completion and maternal influenza vaccination were reported by tabular methods and with a Pearson's chi-squared test.

**Predictive model.** Logistic regression as shown in **Equation 1.1** was used to estimate log odds (not presented), followed by the prediction of marginal proportions (as shown in **Equation 1.2** and **Equation 1.3**, using the log odds calculated in **Equation 1.1** by influenza vaccine status) and risk differences (as shown in **Equation 1.4**, using the marginal proportions calculated in **Equation 1.2** and **Equation 1.3**) of child vaccine series completion ( $VAX = 1$ ) by prenatal influenza vaccine receipt ( $FLUVAX$ ) after adjusting for covariate vector  $\mathbf{Z}$  (maternal race/ethnicity, insurance type, maternal age, maternal education, parity, and marital status).

**Equation 1.1.** Logistic regression model for Aim 1 Hypothesis 1.

$$\text{Log odds}(VAX = 1) = \beta_0 + \beta_1 FLUVAX + \beta_z \mathbf{Z}$$

**Equation 1.2.** Calculation of marginal proportion for Aim 1 Hypothesis 1 if  $FLUVAX=1$ .

$$\Pr(VAX = 1 | FLUVAX = 1)$$

$$= \sum_z \left[ \left[ \frac{\exp(\text{Log odds}(VAX = 1 | FLUVAX = 1, Z = z))}{1 + \exp(\text{Log odds}(VAX = 1 | FLUVAX = 1, Z = z))} \right] * \Pr(Z = z) \right]$$

**Equation 1.3.** Calculation of marginal proportion for Aim 1 Hypothesis 1 if  $FLUVAX=0$ .

$$\Pr(VAX = 1|FLUVAX = 0)$$

$$= \sum_z \left[ \frac{\exp(\text{Log odds}(VAX = 1|FLUVAX = 0, Z = z))}{1 + \exp(\text{Log odds}(VAX = 1|FLUVAX = 0, Z = z))} \right] * \Pr(Z = z)$$

**Equation 1.4.** Calculation of risk difference for Aim 1 Hypothesis 1.

$$\text{Risk difference} = \Pr(VAX = 1|FLUVAX = 1) - \Pr(VAX = 1|FLUVAX = 0)$$

**Aim 1. Hypothesis 2.** Among those who did not have the influenza vaccine during pregnancy, there will be a difference in up-to-date vaccination status in the children of mothers who indicated concern about side effects of the influenza vaccine compared to those who did not.

**Descriptive analysis.** Child vaccine series completion and responses to the questions regarding side effects were reported by tabular methods and with a Pearson's chi-squared test.

**Predictive model.** Logistic regression as shown in **Equation 2.1** was used to estimate log odds (not presented), followed by the prediction of marginal proportions (as shown in **Equation 2.2** and **Equation 2.3**, using the log odds calculated in **Equation 2.1** by concern about side effects) and risk differences (as shown in **Equation 2.4**, using the marginal proportions calculated in **Equation 2.2** and **Equation 2.3**) of child vaccine series completion ( $VAX = 1$ ) by concern about side effects of the influenza vaccine (for mother: MOTHER; or for baby: BABY) after adjusting for covariate vector **Z** (maternal race/ethnicity, insurance type, maternal age, maternal education, parity, and marital status) among women who did not have the influenza vaccine during pregnancy. Each concern was evaluated separately since mothers were able to select multiple reasons for choosing not to have the influenza vaccine.

**Equation 2.1.** Logistic regression model for Aim 1 Hypothesis 2.

$$\text{Log odds}(VAX = 1) = \beta_0 + \beta_1(MOTHER \text{ or } BABY) + \beta_z Z$$

**Equation 2.2.** Calculation of marginal proportion for Aim 1 Hypothesis 2 if

MOTHER or BABY=1.

$$\Pr(VAX = 1|(MOTHER \text{ or } BABY) = 1)$$

$$= \sum_z \left[ \left[ \frac{\exp(\text{Log odds}(VAX = 1|(MOTHER \text{ or } BABY) = 1, Z = z))}{1 + \exp(\text{Log odds}(VAX = 1|(MOTHER \text{ or } BABY) = 1, Z = z))} \right] * \Pr(Z = z) \right]$$

**Equation 2.3.** Calculation of marginal proportion for Aim 1 Hypothesis 2 if

MOTHER or BABY=0.

$$\Pr(VAX = 1|(MOTHER \text{ or } BABY) = 0)$$

$$= \sum_z \left[ \left[ \frac{\exp(\text{Log odds}(VAX = 1|(MOTHER \text{ or } BABY) = 0, Z = z))}{1 + \exp(\text{Log odds}(VAX = 1|(MOTHER \text{ or } BABY) = 0, Z = z))} \right] * \Pr(Z = z) \right]$$

**Equation 2.4.** Calculation of risk difference for Aim 1 Hypothesis 2.

$$\begin{aligned} \text{Risk difference} &= \Pr(VAX = 1|(MOTHER \text{ or } BABY) = 1) \\ &- \Pr(VAX = 1|(MOTHER \text{ or } BABY) = 0) \end{aligned}$$

**Aim 1. Hypothesis 3.** There will be a difference in up-to-date vaccination status of individual vaccines in children of mothers who received the influenza vaccine during pregnancy and those who did not.

**Descriptive analysis.** Child vaccine completion for each individual vaccine and maternal influenza vaccination was reported by tabular methods and with a Pearson's chi-squared test. Individual vaccines included the following: DTaP, polio, MMR, Haemophilus influenzae type B, hepatitis B, varicella, and PCV.

**Predictive model.** Logistic regression as shown in **Equation 3.1** was used to estimate log odds (not presented), followed by the prediction of marginal proportions (as shown in **Equation 3.2** and **Equation 3.3**, using the log odds calculated in **Equation 3.1** by influenza vaccine status) and risk differences (as shown in **Equation 3.4**, using the marginal proportions calculated in **Equation 3.2** and **Equation 3.3**) of individual child vaccine completion ( $INDIVVAX = 1$ ) by prenatal influenza vaccine receipt ( $FLUVAX$ ) after adjusting for covariate vector  $\mathbf{Z}$  (maternal race/ethnicity, insurance type, maternal age, maternal education, parity, and marital status).

**Equation 3.1.** Logistic regression model for Aim 1 Hypothesis 3.

$$\text{Log odds}(INDIVVAX = 1) = \beta_0 + \beta_1 FLUVAX + \beta_z \mathbf{Z}$$

**Equation 3.2.** Calculation of marginal proportion for Aim 1 Hypothesis 3.

$$\Pr(INDIVVAX = 1 | FLUVAX = 1)$$

$$= \sum_z \left[ \left[ \frac{\exp(\text{Log odds}(INDIVVAX = 1 | FLUVAX = 1, Z = z))}{1 + \exp(\text{Log odds}(INDIVVAX = 1 | FLUVAX = 1, Z = z))} \right] * \Pr(Z = z) \right]$$

**Equation 3.3.** Calculation of marginal proportion for Aim 1 Hypothesis 3.

$$\Pr(INDIVVAX = 1 | FLUVAX = 0)$$

$$= \sum_z \left[ \left[ \frac{\exp(\text{Log odds}(INDIVVAX = 1 | FLUVAX = 0, Z = z))}{1 + \exp(\text{Log odds}(INDIVVAX = 1 | FLUVAX = 0, Z = z))} \right] * \Pr(Z = z) \right]$$

**Equation 3.4.** Calculation of risk difference for Aim 1 Hypothesis 3.

$$\text{Risk difference} = \Pr(INDIVVAX = 1 | FLUVAX = 1) - \Pr(INDIVVAX = 1 | FLUVAX = 0)$$

**Aim 2. Hypothesis 1 - Exploratory.** There will be a difference in up-to-date vaccination status between the children of mothers who had OOH births and those who did not have OOH births.

**Descriptive analysis.** Child vaccine series completion and OOH birth was reported by tabular methods and with a Pearson's chi-squared test.

**Predictive model.** Logistic regression as shown in **Equation 4.1** was used to estimate log odds (not presented), followed by the prediction of marginal proportions (as shown in **Equation 4.2** and **Equation 4.3**, using the log odds calculated in **Equation 4.1** by birthing place) and risk differences (as shown in **Equation 4.4**, using the marginal proportions calculated in **Equation 4.2** and **Equation 4.3**) of child vaccine series completion ( $VAX = 1$ ) by OOH birth status (OOH) after adjusting for covariate vector  $\mathbf{Z}$  (maternal race/ethnicity, insurance type, maternal age, maternal education, parity, and marital status).

**Equation 4.1.** Logistic regression model for Aim 2 Hypothesis 1.

$$\text{Log odds}(VAX = 1) = \beta_0 + \beta_1 OOH + \beta_z \mathbf{Z}$$

**Equation 4.2.** Calculation of marginal proportion for Aim 2 Hypothesis 1.

$$\Pr(VAX = 1|OOH = 1)$$

$$= \sum_z \left[ \frac{\exp(\text{Log odds}(VAX = 1|OOH = 1, Z = z))}{1 + \exp(\text{Log odds}(VAX = 1|OOH = 1, Z = z))} * \Pr(Z = z) \right]$$

**Equation 4.3.** Calculation of marginal proportion for Aim 2 Hypothesis 1.

$$\Pr(VAX = 1|OOH = 0)$$

$$= \sum_z \left[ \frac{\exp(\text{Log odds}(VAX = 1|OOH = 0, Z = z))}{1 + \exp(\text{Log odds}(VAX = 1|OOH = 0, Z = z))} * \Pr(Z = z) \right]$$

**Equation 4.4.** Calculation of risk difference for Aim 2 Hypothesis 1.

$$\text{Risk difference} = \Pr(VAX = 1|OOH = 1) - \Pr(VAX = 1|OOH = 0)$$

**Aim 2. Hypothesis 2 - Exploratory.** There will be a difference in OOH births between mothers who had the influenza vaccine during pregnancy and those who did not.

**Descriptive analysis.** Birthing location and maternal influenza vaccination during pregnancy was reported by tabular methods and with a Pearson's chi-squared test.

**Predictive analysis.** Logistic regression as shown in **Equation 5.1** was used to estimate log odds (not presented), followed by the prediction of marginal proportions (as shown in **Equation 5.2** and **Equation 5.3**, using the log odds calculated in **Equation 5.1** by influenza vaccine status) and risk differences (as shown in **Equation 5.4**, using the marginal proportions calculated in **Equation 5.2** and **Equation 5.3**) of OOH birth (OOH = 1) by prenatal influenza vaccine receipt (FLUVAX) after adjusting for covariate vector **Z** (maternal race/ethnicity, insurance type, maternal age, maternal education, parity, and marital status).

**Equation 5.1.** Logistic regression model for Aim 2 Hypothesis 2.

$$\text{Log odds}(\text{OOH} = 1) = \beta_0 + \beta_1 \text{FLUVAX} + \beta_z \mathbf{Z}$$

**Equation 5.2.** Calculation of marginal proportion for Aim 2 Hypothesis 2.

$$\text{Pr}(\text{OOH} = 1 | \text{FLUVAX} = 1)$$

$$= \sum_z \left[ \frac{\exp(\text{Log odds}(\text{OOH} = 1 | \text{FLUVAX} = 1, Z = z))}{1 + \exp(\text{Log odds}(\text{OOH} = 1 | \text{FLUVAX} = 1, Z = z))} \right] * \text{Pr}(Z = z)$$

**Equation 5.3.** Calculation of marginal proportion for Aim 2 Hypothesis 2.

$$\text{Pr}(\text{OOH} = 1 | \text{FLUVAX} = 0)$$

$$= \sum_z \left[ \frac{\exp(\text{Log odds}(\text{OOH} = 1 | \text{FLUVAX} = 0, Z = z))}{1 + \exp(\text{Log odds}(\text{OOH} = 1 | \text{FLUVAX} = 0, Z = z))} \right] * \text{Pr}(Z = z)$$

**Equation 5.4.** Calculation of risk difference for Aim 2 Hypothesis 2.

$$\text{Risk difference} = \text{Pr}(\text{OOH} = 1 | \text{FLUVAX} = 1) - \text{Pr}(\text{OOH} = 1 | \text{FLUVAX} = 0)$$

## Chapter 4: Results

### Maternal and Child Characteristics

A total of 4,111 mothers were available for analysis from MN PRAMS 2009-2011. From MN PRAMS data, 23 children were reported as being deceased and the mother-child dyads containing these children were excluded from the analyses. After merging the MIIC dataset with the MN PRAMS dataset, 6 mothers (0.13% weighted) from the MN PRAMS dataset did not have a matching child in the MIIC dataset and were excluded from the analyses. The mean analytical weight was 48.04 (standard deviation: 23.39; minimum: 4.45; maximum: 152.47), meaning the average respondent represented approximately 48 Minnesotan mothers. The final unweighted sample size was 4,082 mothers, representing 196,096 Minnesotan mothers. A total of 2,618 women (65.0% weighted) received an influenza vaccine during pregnancy while 1,404 (35.1% weighted) did not. A total of 26 women (0.6% weighted) had OOH births while 4,056 women (99.4% weighted) gave birth in hospitals. Only 86 children (2.29% weighted) had zero vaccinations in the dataset, while 3,936 children (96.11% weighted) had two or more vaccinations in the dataset.

Maternal and child demographic characteristics by influenza vaccination status are reported in **Table 3**. Percentages are weighted to adjust for complex survey design and non-response, while sample sizes are unweighted. The majority of the mothers in the sample were non-Hispanic white (75.06% weighted), were between the ages of 18 and 44 (98.36% weighted), had more than a high school education (66.88% weighted), were married (68.24% weighted), had income \$25,000/year or greater (69.51% weighted), had one or more previous live births (59.23% weighted), and were insured privately through

an employer-based plan (59.55% weighted). The weighted mean age of the children at the time the MIIC data was provided (January 2015) was 54.44 months. There were no differences by maternal race/ethnicity, parity, or child age in the uptake of the influenza vaccine during pregnancy, but there were differences in uptake of the influenza vaccine during pregnancy by maternal age, maternal education, household income, insurance type, and marital status. Demographic characteristics by birthing place are not shown due to sample size limitations in the OOH birth group and the potential for subjects to be identified.

<b>Table 3. Maternal and child characteristics.</b>				
	<i>Total N (weighted column %)*</i>	<i>Had influenza vaccine during pregnancy n (weighted column %)*</i>	<i>Did not have influenza vaccine during pregnancy n (weighted column %)*</i>	<i>p-value**</i>
<b>Number of Participants</b>	4,022	2,618	1,404	--
<b>Maternal Race/ Ethnicity</b>				
				0.312
White Non-Hispanic	2,465 (75.06%)	1,613 (74.73%)	852 (75.67%)	
Black Non-Hispanic	528 (7.43%)	324 (7.01%)	204 (8.21%)	
Hispanic	259 (7.55%)	171 (7.77%)	88 (7.13%)	
Other Non-Hispanic	699 (9.96%)	467 (10.49%)	232 (8.99%)	
<b>Maternal Age</b>				
				<0.001
<18 years	76 (1.38%)	52 (1.27%)	24 (1.58%)	
18-24 years	961 (21.50%)	565 (18.99%)	396 (26.15%)	
25-29 years	1,327 (33.60%)	866 (33.76%)	461 (33.31%)	
30-44 years	1,651 (43.26%)	1,132 (45.82%)	519 (38.53%)	
45+ years	7 (0.26%)	3 (0.17%)	4 (0.43%)	
<b>Maternal Education</b>				
				<0.001
Less than high school	407 (9.67%)	266 (9.71%)	141 (9.59%)	
High school	886 (23.45%)	508 (19.91%)	378 (29.99%)	
More than high school	2,688 (66.88%)	1,816 (70.38%)	872 (60.42%)	
<b>Household Income</b>				
				<0.001
<\$10,000	658 (13.24%)	388 (11.55%)	270 (16.35%)	
\$10,000-\$24,999	684 (17.26%)	402 (15.48%)	282 (20.54%)	
\$25,000-\$49,999	826 (22.63%)	511 (21.42%)	315 (24.86%)	
\$50,000+	1,704 (46.88%)	1,217 (51.55%)	487 (38.24%)	



<b>Table 3 Continued.</b>				
	<i>Total N (weighted column %)*</i>	<i>Had influenza vaccine during pregnancy n (weighted column %)*</i>	<i>Did not have influenza vaccine during pregnancy n (weighted column %)*</i>	<i>p-value**</i>
<b>Parity</b>				0.961
No previous live birth	1,640 (40.77%)	1,074 (40.74%)	566 (40.83%)	
One or more previous live births	2,317 (59.23%)	1,500 (59.26%)	817 (59.17%)	
<b>Insurance Type</b>				<0.001
Private	2,166 (59.55%)	1,517 (63.89%)	645 (51.33%)	
Public	1,547 (36.54%)	926 (32.81%)	620 (43.60%)	
None	46 (0.97%)	24 (0.74%)	22 (1.40%)	
Other	119 (2.94%)	68 (2.56%)	51 (3.67%)	
<b>Marital Status</b>				<0.001
Married	2,539 (68.24%)	1,718 (70.89%)	821 (63.34%)	
Other	1,482 (31.76%)	900 (29.11%)	582 (36.66%)	
<b>Child Mean Age in Months</b>	54.55	54.33	54.73	0.297
*Missing influenza vaccine status for 60 mothers reduced the sample size from n = 4,082 to n = 4,022 available for analysis for Aim 1. Percentages may not add up to 100% due to rounding. The total n for each characteristic here may not add up to 4,022 due to missing data.				
**P-values calculated using t-tests and Pearson's chi-squared tests, when appropriate.				

## Aim 1

Results for Aim 1 are shown in **Tables 4, 5, and 6**. Vaccination coverage estimates are weighted to adjust for complex survey design and non-response, while sample sizes are unweighted. Covariate-adjusted models were adjusted for race/ethnicity, insurance type, maternal age, maternal education, parity, and marital status. Income was not included in adjusted models due to collinearity with insurance type. Additionally, income was not a significant predictor of the outcomes even when insurance type was removed from the models, while insurance type remained significant. Insurance type was also chosen over income for inclusion due to the potential for bias in self-report of income. For all hypotheses, risk differences were qualitatively consistent before and after adjustment, with covariate adjustment having a slightly attenuating impact on point

estimates. Unweighted estimates (not shown) were also qualitatively consistent with the appropriate, weighted estimates.

#### *Aim 1 Hypothesis 1*

Results for Aim 1 Hypothesis 1 are shown in **Table 4**. The proportion of vaccine series completion in children of mothers who received the influenza vaccine during pregnancy (73.50%) in the weighted and adjusted model was similar to national and Minnesota estimates of vaccination coverage from **Table 1**. In both unadjusted weighted and adjusted weighted models, those who had an influenza vaccine during pregnancy were more likely than those who did not have an influenza vaccine during pregnancy to have children who were up-to-date on the full series of vaccines by 36 months. Vaccine series completion was 10.86% higher (95% confidence interval (CI) 7.33%-14.40%, adjusted and weighted model) in children of mothers who had the influenza vaccine during pregnancy compared to those who did not.

<b><i>Table 4. Aim 1, Hypothesis 1 – Risk and risk difference predictions from logistic regression models using survey-sampling procedures.</i></b>					
	<b><i>Flu Vaccine Receipt (95% Confidence Interval)</i></b>	<b><i>No Flu Vaccine Receipt (95% Confidence Interval)</i></b>	<b><i>Risk Difference (95% Confidence Interval)</i></b>	<b><i>p-value*</i></b>	<b><i>n for model</i></b>
<b><i>Vaccination Series Completion</i></b>					
Unadjusted – Weighted %	73.39% (71.54%, 75.24%)	61.81% (58.96%, 64.66%)	11.58% (8.18%, 14.98%)	<0.001	4,022
Adjusted** – Weighted %	73.50% (71.56%, 75.43%)	62.64% (59.70%, 65.57%)	10.86% (7.33%, 14.40%)	<0.001	3,723
<i>*P-values calculated for the risk difference with the survey equivalent of a two sample t-test.</i>					
<i>**Models adjusted for: Race/Ethnicity, maternal age, education, marital status, parity, and insurance type.</i>					

#### *Aim 1 Hypothesis 2*

Results for Aim 1 Hypothesis 2 are shown in **Table 5**. Child vaccine series completion was not different among those who did and did not indicate concern about

maternal side effects as a reason for not having the influenza vaccine during pregnancy (54.70% vs. 57.43% respectively, adjusted and weighted model). Child vaccine series completion was 10.52% lower (95% CI -19.43%, -1.61%, adjusted and weighted model) among women who indicated concern about side effects for the baby as a reason for not receiving the influenza vaccine during pregnancy compared to those who indicated this was not a reason for not having the influenza vaccine during pregnancy.

<b>Table 5. Aim 1, Hypothesis 2 – Risk and risk difference predictions from logistic regression models using survey-sampling procedures.</b>					
	<b>Worried About Side Effects for Self (95% Confidence Interval)</b>	<b>Not Worried About Side Effects for Self (95% Confidence Interval)</b>	<b>Risk Difference (95% Confidence Interval)</b>	<b>p-value*</b>	<b>n for model</b>
<b>Vaccination Series Completion</b>					
Unadjusted – Weighted %	53.44% (47.19%, 59.70%)	56.81% (50.76%, 62.85%)	-3.36% (-12.06%, 5.33%)	0.448	660
Adjusted** – Weighted %	54.70% (48.22%, 61.18%)	57.43% (51.22%, 63.63%)	-2.72% (-11.63%, 6.19%)	0.549	608
	<b>Worried Flu Shot Might Harm Baby (95% Confidence Interval)</b>	<b>Not Worried Flu Shot Might Harm Baby (95% Confidence Interval)</b>	<b>Risk Difference (95% Confidence Interval)</b>	<b>p-value</b>	<b>n for model</b>
<b>Vaccination Series Completion</b>					
Unadjusted – Weighted %	48.56% (42.17%, 54.94%)	61.43% (55.55%, 67.30%)	-12.87% (-21.55%, -4.19%)	0.004	656
Adjusted** – Weighted %	50.85% (44.24%, 57.45%)	61.37% (55.29%, 67.45%)	-10.52% (-19.43%, -1.61%)	0.021	604
*P-values calculated for the risk difference with the survey equivalent of a two sample t-test.					
**Models adjusted for: Race/Ethnicity, maternal age, education, marital status, parity, and insurance type.					

### *Aim 1 Hypothesis 3*

Results for Aim 1 Hypothesis 3 are shown in **Table 6**. Those who had an influenza vaccine during pregnancy were more likely than those who did not have an influenza vaccine during pregnancy to have children who were up-to-date on each individual vaccine by 36 months. Covariate-adjusted and weighted risk differences for

each individual vaccine were fairly consistent, ranging from 7.83% (95% CI 5.37%, 10.30%) for the Hib vaccine to 10.06% (95% CI 7.29%, 12.83%) for the hepatitis B vaccine.

<b>Table 6. Aim 1, Hypothesis 3 – Risk and risk difference predictions from logistic regression models using survey-sampling procedures.</b>					
	<b>Flu Vaccine Receipt (95% Confidence Interval)</b>	<b>No Flu Vaccine Receipt (95% Confidence Interval)</b>	<b>Risk Difference (95% Confidence Interval)</b>	<b>p-value*</b>	<b>n for model</b>
<b><i>DTaP Vaccine Completion</i></b>					
Unadjusted – Weighted %	86.92% (85.50%, 88.33%)	76.78% (74.28%, 79.28%)	10.14% (7.27%, 13.01%)	<0.001	4,022
Adjusted** – Weighted %	86.96% (85.47%, 88.45%)	78.27% (75.77%, 80.78%)	8.69% (5.76%, 11.61%)	<0.001	3,723
<b><i>Polio Vaccine Completion</i></b>					
Unadjusted – Weighted %	93.48% (92.47%, 94.49%)	84.76% (82.65%, 86.88%)	8.72% (6.37%, 11.06%)	<0.001	4,022
Adjusted** – Weighted %	93.57% (92.53%, 94.61%)	85.06% (82.88%, 87.23%)	8.51% (6.10%, 10.92%)	<0.001	3,723
<b><i>MMR Vaccine Completion</i></b>					
Unadjusted – Weighted %	92.11% (90.98%, 93.23%)	83.68% (81.46%, 85.91%)	8.43% (5.93%, 10.92%)	<0.001	4,022
Adjusted** – Weighted %	91.84% (90.63%, 93.05%)	83.87% (81.61%, 86.13%)	7.97% (5.41%, 10.53%)	<0.001	3,723
<b><i>Hib Vaccine Completion</i></b>					
Unadjusted – Weighted %	92.74% (91.67%, 93.81%)	84.07% (81.92%, 86.21%)	8.67% (6.27%, 11.07%)	<0.001	4,022
Adjusted** – Weighted %	92.47% (91.32%, 93.62%)	84.63% (82.46%, 86.81%)	7.83% (5.37%, 10.30%)	<0.001	3,723
<b><i>Hepatitis B Vaccine Completion</i></b>					
Unadjusted – Weighted %	90.00% (88.76%, 91.23%)	79.81% (77.46%, 82.16%)	10.19% (7.53%, 12.84%)	<0.001	4,022
Adjusted** – Weighted %	90.02% (88.73%, 91.31%)	79.96% (77.52%, 82.40%)	10.06% (7.29%, 12.83%)	<0.001	3,723
(continued on the next page)					

<i>Table 6 Continued.</i>					
	<i>Flu Vaccine Receipt (95% Confidence Interval)</i>	<i>No Flu Vaccine Receipt (95% Confidence Interval)</i>	<i>Risk Difference (95% Confidence Interval)</i>	<i>p-value*</i>	<i>n for model</i>
<b><i>Varicella Vaccine Completion</i></b>					
Unadjusted – Weighted %	91.02% (89.82%, 92.22%)	80.83% (78.51%, 83.16%)	10.18% (7.56%, 12.80%)	<0.001	4,022
Adjusted** – Weighted %	90.97% (89.71%, 92.23%)	81.38% (79.02%, 83.74%)	9.58% (6.91%, 12.26%)	<0.001	3,723
<b><i>PCV Vaccine Completion</i></b>					
Unadjusted – Weighted %	82.36% (80.75%, 83.96%)	71.83% (69.17%, 74.48%)	10.53% (7.43%, 13.63%)	<0.001	4,022
Adjusted** – Weighted %	82.34% (80.66%, 84.02%)	72.98% (70.28%, 75.68%)	9.36% (6.17%, 12.56%)	<0.001	3,723
*P-values calculated for the risk difference with the survey equivalent of a two sample t-test.					
**Models adjusted for: Race/Ethnicity, maternal age, education, marital status, parity, and insurance type.					

## **Aim 2 – Exploratory**

Results for the exploratory Aim 2 are shown in **Table 7**. Vaccination coverage and OOH birth estimates are weighted to adjust for complex survey design and non-response, while sample sizes are unweighted. Covariate-adjusted models were adjusted for race/ethnicity, insurance type, maternal age, maternal education, parity, and marital status. Income was not included in adjusted models due to collinearity with insurance type. Additionally, income was not a significant predictor of the outcomes even when insurance type was removed from the models, while insurance type remained significant. Insurance type was also chosen over income for inclusion due to the potential for bias in self-report of income. For both hypotheses, risk differences were qualitatively consistent before and after adjustment, with covariate adjustment having an attenuating impact on point estimates. Unweighted estimates (not shown) were also qualitatively consistent with the appropriate, weighted estimates.

### *Aim 2 Hypothesis 1*

In the adjusted and weighted model, mothers who had OOH births were 34.74% less likely (95% CI -59.76%, -9.72%) to have children who were up-to-date on the vaccine series compared to mothers who gave birth in hospitals (35.23% vs. 69.97%, respectively).

### *Aim 2 Hypothesis 2*

In the adjusted and weighted model, mothers who had influenza vaccines during pregnancy were 0.79% less likely (95% CI -1.43%, -0.14%) to have OOH births than mothers who did not have an influenza vaccine during pregnancy (0.28% vs. 1.06%, respectively).

<b>Table 7. Aim 2 – Risk and risk difference predictions from logistic regression models using survey-sampling procedures.</b>					
<i>Aim 2 Hypothesis 1</i>					
	<b>OOH Births (95% Confidence Interval)</b>	<b>Hospital Births (95% Confidence Interval)</b>	<b>Risk Difference (95% Confidence Interval)</b>	<b>p-value*</b>	<b>n for model</b>
<b>Vaccination Series Completion</b>					
Unadjusted – Weighted %	25.70% (6.44%, 44.96%)	69.66% (68.09%, 71.23%)	-43.96% (-63.28%, -24.63%)	<0.001	4,082
Adjusted** – Weighted %	35.23% (10.27%, 60.20%)	69.97% (68.35%, 71.60%)	-34.74% (-59.76%, -9.72%)	0.007	3,770
<i>Aim 2 Hypothesis 2</i>					
	<b>Flu Vaccine Receipt (95% Confidence Interval)</b>	<b>No Flu Vaccine Receipt (95% Confidence Interval)</b>	<b>Risk Difference (95% Confidence Interval)</b>	<b>p-value*</b>	<b>n for model</b>
<b>OOH Birth</b>					
Unadjusted – Weighted %	0.22% (0.04%, 0.41%)	1.28% (0.66%, 1.91%)	-1.06% (-1.71%, -0.41%)	0.001	4,022
Adjusted** – Weighted %	0.28% (0.06%, 0.50%)	1.06% (0.45%, 1.68%)	-0.79% (-1.43%, -0.14%)	0.018	3,436
<i>*P-values calculated for the risk difference with the survey equivalent of a two sample t-test.</i>					
<i>**Models adjusted for: Race/Ethnicity, maternal age, education, marital status, parity, and insurance type.</i>					

## Chapter 5: Discussion

Vaccination is an essential component of the public health system in the United States. Currently, vaccine coverage is below ideal levels for several individual vaccines and for the full childhood series recommended to occur by 19 months of age. Outbreaks of vaccine-preventable illnesses have continued to arise. Thus far, interventions aiming to increase child vaccination, usually consisting of parent education at or near the time of recommended child vaccinations, have had little effect on vaccine uptake (Kaufman et al., 2013; Sadaf, Richards, Glanz, Salmon, & Omer, 2013). Few studies have investigated distal factors in relation to or as intervention points for increasing vaccine uptake in early childhood. This study demonstrates a relationship between maternal health choices and child vaccine uptake. These findings could lead to new strategies for intervention.

### *Influenza Vaccination During Pregnancy*

Prenatal influenza vaccination was investigated in this study as a predictor of early childhood vaccination. Early childhood vaccine series completion was over 10% higher in children of mothers who had the influenza vaccination during pregnancy compared to children of mothers who did not have an influenza vaccination during pregnancy. Not only was there a difference in the uptake of the entire vaccine series by maternal influenza vaccination status, there were differences for each vaccine in the series alone. While there may be an expectation for differential incomplete vaccination based on type of vaccine due to the recent controversy surrounding the MMR vaccine and previous research indicating that some parents would be more likely to refuse or delay some vaccines over others and for different reasons (Dempsey et al., 2011; Freed et al., 2010), risk differences were fairly consistent across individual vaccines. Risk differences

for vaccines occurring only once in the series and those occurring multiple times were also consistent.

Still, in this population, vaccine series completion in both children of mothers who had the influenza vaccine during pregnancy and those who did not was below the HP2020 goal of 80% (U.S. Department of Health and Human Services, 2015). Among children of mothers who did have the influenza vaccine during pregnancy, vaccine completion was near or above HP2020 goals for some individual vaccines, yet below for others. Among children of mothers who did not have the influenza vaccine during pregnancy, vaccine completion was below HP2020 goals for all individual vaccines. Increases in early childhood vaccine uptake are necessary all around in order to meet and exceed national goals.

Influenza vaccination is recommended for all pregnant women and may occur at any point during pregnancy (Centers for Disease Control and Prevention, 2013d), but uptake remains lower than ideal. While influenza vaccination during pregnancy was treated as a predictor in the present study, it is an essential component of the preventive health care system itself. Prenatal influenza vaccination is important in protecting infants from influenza since they cannot be vaccinated until they are 6 months old (American College of Obstetricians and Gynecologists, 2014; Centers for Disease Control and Prevention, 2015a). Prenatal influenza vaccination confers limited immunity in the immediate neonatal period, but also protects the infant by decreasing the possibility of the mother contracting influenza and passing it to the child (American College of Obstetricians and Gynecologists, 2014). Caregivers, household members, and close contacts of children under 6 years of age are also encouraged to be vaccinated for



influenza (Grohskopf et al., 2013). The uptake of the influenza vaccine during pregnancy has slowly increased over the past several years, but is still low (Ding et al., 2014). Influenza vaccine coverage in this population of Minnesotan mothers was 65.0%, which was higher than the most recent national estimate where 52.2% of pregnant women were protected during the influenza season (Ding et al., 2014). Currently, the HP2020 objective for prenatal influenza vaccination is listed as developmental and does not provide clear baseline or goal percentages (U.S. Department of Health and Human Services, 2015).

Identifying new targets and methods for intervention is important in order to increase individual vaccine and vaccine series completion. Few studies have investigated relationships between maternal influenza vaccination and child vaccination, but one novel intervention study found that mothers who had a short intervention and reported the intention to have prenatal influenza vaccinations were also more likely to report intent to vaccinate their infants for influenza (Frew et al., 2013). The present study provides evidence of a relationship between maternal influenza vaccination and early childhood vaccination, suggesting that either an underlying belief system or underlying circumstances, such as differences in access or provider practices, is leading to differences in early childhood vaccination in these groups.

There is more work to do to increase childhood vaccine uptake in both the general population and among subgroups. This study demonstrates that childhood vaccination is associated with maternal influenza vaccination during pregnancy and suggests there may be an opportunity for prenatal intervention for childhood vaccines. Mothers who do not receive the influenza vaccine during pregnancy, either due to refusal of the vaccine or

other circumstances, may be targeted for prenatal interventions aiming to increase early childhood vaccination.

#### *Concern Regarding Side Effects of Maternal Influenza Vaccination*

In this study, those who indicated concern about side effects for the infant as a reason for not having the influenza vaccine during pregnancy had children with lower vaccination series completion compared to those who did not indicate this concern.

Interestingly, among those who did not have the influenza vaccine during pregnancy, the current study showed no relationship between concern for maternal side effects of the prenatal influenza vaccine and future child vaccination. These results suggest, at least, that different kinds of concerns may be driving the refusal of maternal vaccination and the refusal of child vaccination and, at most, that different theoretical approaches may be necessary when developing maternal compared to early childhood vaccine intervention programs that target those who are hesitant.

Previous studies have identified concerns by mothers about side effects for both mother and infant regarding the influenza vaccination during pregnancy. One recent study investigating prenatal influenza coverage created a composite variable of maternal responses regarding concern about maternal or infant side effects (Ding et al., 2014). The present study indicates that there may be evidence for heterogeneity in this group and that combining response categories may not be appropriate in the future in studies where childhood vaccination is an outcome of interest, though this should be investigated further. There may be differences in the overall belief systems of mothers who refuse influenza vaccines due to concerns about maternal side effects compared to those who refuse due to concerns about infant side effects. If these differences are confirmed in

future research, distinctive approaches to interventions may be considered for these subgroups.

Differences in beliefs among mothers who did and did not have the influenza vaccine could not be explored here, nor could nuances in child vaccination between beliefs in mothers who did receive the influenza vaccination, since these prenatal influenza vaccination questions were not asked of mothers who were vaccinated for influenza prenatally. Future researchers may consider asking questions about beliefs regarding prenatal influenza vaccination to mothers whether they intend to have or have had the vaccine or not.

Vaccine-hesitant beliefs are often cited as reasons for refusing early childhood vaccines. If beliefs about prenatal influenza vaccination are related to early childhood vaccination, there may be the possibility of identifying those at risk of not vaccinating during the prenatal period. Further exploration of the relationship between prenatal influenza vaccination beliefs and early childhood vaccination could lead to the development of earlier and more effective vaccination programs.

### *Birth Place*

The relationships between birthing place and maternal and early childhood vaccination were explored here due to the similarities in beliefs expressed in previous studies by mothers when making decisions about birthing place, especially among those who choose to have OOH births, and maternal and early childhood vaccination. The investigation of birthing place as a predictor of childhood vaccination uptake and its relationship with prenatal influenza vaccination was exploratory in nature, particularly due to the limitation in the sample size of the OOH birth group. It is important to note

that the very small sample size for the OOH birth group also requires there be extreme caution in the interpretation of the results. The differences in point estimates after adjustment and the wide confidence intervals for both exploratory hypotheses in Aim 2 reflect the small sample size of the OOH birth group.

In this population, child vaccine series completion was substantially lower in children of mothers who delivered in OOH settings compared to children whose mothers had hospital births. The wide confidence interval for the risk difference in child vaccine series completion for those who had OOH births compared to those who had hospital births reflects the small sample size for those in the OOH birth group. Despite the small sample size, this large point estimate does suggest that this relationship should be further explored. While the overall weighted percentage of OOH births in this population was very small, the percentage of Minnesota women who have OOH births is rapidly rising. Future research should focus on confirming whether or not a relationship exists between OOH birth and child vaccination. Vaccination interventions targeting women who plan to have OOH births may be indicated if this relationship is confirmed with a larger sample of mothers who deliver in OOH settings.

While the risk difference in OOH birth was very small as predicted by uptake of influenza vaccination during pregnancy, it is important to take into account the underlying proportion of the population having OOH births. In Minnesota, 1.24% of the population had OOH births in 2012 (MacDorman et al., 2014). This is a very small fraction of the population, though this is double the proportion of those who had OOH births in 2004 (MacDorman et al., 2014) and is expected to continue rising, particularly

as more women choose to deliver in birth centers (American Association of Birth Centers, 2013).

It is unlikely that the act of refusing prenatal influenza vaccination or otherwise not receiving a prenatal influenza vaccination is influencing the choice of birthing place, especially since mothers who choose to deliver in OOH settings generally have an idea of where they would like to deliver before they choose their provider (Hodnett, 1989). That is, those who refuse influenza vaccination during pregnancy and go on to deliver in OOH settings likely already have a plan to have an OOH delivery before the time when prenatal influenza vaccination would be given. It is also plausible that there could be differential recommendation in prenatal influenza vaccination by providers who care for patients who deliver in OOH settings compared to those who care for patients delivering in hospitals or there could be an underlying belief system influencing both of those choices.

If the relationship between OOH birth and childhood vaccination is confirmed in future studies, it will be important to monitor any vaccination trends in this population. Another avenue that should be explored is whether or not these women are seeing the same few providers. Monitoring of vaccination trends in this subgroup may be particularly important if the women who deliver in OOH settings are in the same social networks and then also have children who are less likely to be fully vaccinated, where community immunity would then be very low.

Certainly, choice of birthing place may not impact vaccine uptake itself and whether or not a mother chooses to have an influenza vaccine during pregnancy may not influence her choice about where to deliver, but these choices may be indicative of a

larger system of beliefs. Prior to this study, only one published study had identified an association between “alternative childbearing” and a vaccination outcome, though that study used vaccination exemptions as the outcome (Gaudino & Robison, 2012). An underlying or larger scale belief system may be influencing the choice of birthing place and also vaccination choices, potentially including delay, refusal, and exemption. Future research may focus on establishing temporality by investigating belief systems encompassing both birthing place and vaccines among newly pregnant women as they make choices about their providers. Research has shown that mothers who want to deliver in OOH settings have made this decision prior to choosing their provider (Hodnett, 1989), which typically occurs in the first trimester, so future research may focus on whether beliefs about and plans for child vaccination are also solidified early in pregnancy or even prior to pregnancy.

While this investigation into birthing place as a predictor of child vaccination is exploratory, these results warrant further research. As this area has been largely unexplored, future research should also explore the vaccine-related beliefs and practices in providers who attend OOH births compared to those who attend hospital births. Provider recommendation remains one of the most important predictors of influenza vaccination (Ding et al., 2014). Whether there are different practices with regard to either prenatal or childhood vaccine recommendations among providers who attend OOH births compared to those who attend hospital births is unknown.

### *Strengths and Limitations*

A strength of this study was the use of two high quality state-level datasets. High quality vaccination data is available for a large population from MIIC. In contrast to

some other sources of vaccination data, like clinics and hospitals, a high-coverage vaccination registry such as MIIC may contain a more representative sample of children throughout the state. Few children were not represented in this dataset and many of the shortcomings, like lack of coverage for providers in non-participating border states, are known. The high coverage of this registry and others like it could be useful if combined with various other state-level representative surveys or datasets. The combination of MIIC and MN PRAMS data allows for the cautious generalization of these results to the population level.

MN PRAMS data has its own strengths, particularly in that the data is rigorously collected. Survey sampling is notoriously difficult and MN PRAMS has managed to acquire a response rate of at least 70% for 2009 and at least 65% for 2010 and 2011 (Centers for Disease Control and Prevention, 2015b) by frequent contacts in various formats and by providing the survey in both English and Spanish (Minnesota Department of Health, n.d.-a). Researchers attempting to do maternal and child vaccine research in the future would be remiss if they did not consider the use of PRAMS data. While it may be appealing to forgo the use of existing data in favor of collecting new data, there remains a wealth of unexplored territory in rigorously collected state-level datasets, particularly when there is the possibility of merging with a large, high quality immunization registry.

The analysis of MN PRAMS data requires the use of survey weights in order to give population-level estimates of health measures. This may be viewed as both a strength and a limitation. As mentioned, survey weighting is important when the goal of an analysis is to make generalizations to a population level and describe the current state

of health in a target population. While the use of survey weights here gives population-level estimates of maternal health measures and appropriate standard error estimates via *statistical* inference, the use of survey weights has been debated in its utility as far as providing *scientific* inference (Rothman et al., 2013). Unweighted analyses (not shown) were conducted and produced qualitatively identical results to those presented here. If weighted results had differed greatly from unweighted results, particularly qualitatively, scientific inference here would be particularly questionable. The results of this study should be interpreted as the weighted average association over the population of mothers and children (born from 2009-2011) in Minnesota. There may be larger, smaller, or no associations among various subgroups of Minnesotan mothers and children. Additionally, these results do not explain the exact causal mechanisms involved.

The largest limitation in this study is its observational design. Observational studies are used in epidemiology when it is impossible or unethical to randomize certain exposures (Rothman, Greenland, & Lash, 2008). It is unethical to randomize influenza vaccination during pregnancy since it is a recommended preventive health intervention, impossible to randomly assign attitudes and beliefs, and impossible to randomize birthing location, though it has been attempted (Hendrix et al., 2009). Due to these factors, we are left with an observational design and must rely on either collecting the highest quality data possible or using the highest quality of data already available in order to answer these questions. MN PRAMS data and MIIC data are the highest quality datasets available, relying on rigorous collection protocols and the expertise of MDH, which address each of the exposures and outcomes of interest for Minnesotan mothers.



Another limitation is the potential for missing data from MIIC. While only six children were completely missing from the MIIC dataset, it is possible that the missing data could be missing not at random. Of those children who were in the dataset but did not have complete vaccination records, it is possible that some children had actually had certain vaccines, but these were not captured by MIIC due to lack of provider reporting or other factors. Despite these issues, MIIC data contains the largest and most complete vaccination data on children in Minnesota.

A limitation of the present study is that the maternal belief questions were not asked of mothers who did have the influenza vaccine during pregnancy. Differences in beliefs among mothers who did and did not have the influenza vaccine could not be explored here, nor could nuances in child vaccination between beliefs in mothers who did receive the influenza vaccination. Researchers may consider expanding these questions to all respondents regardless of influenza vaccine receipt in the future.

Another limitation is that MN PRAMS surveys rely on maternal self-report for the prenatal influenza vaccination item. There is no verification of influenza vaccination during pregnancy, so this response is subject to recall bias. Future research may consider using MIIC to complement MN PRAMS survey responses in order to verify vaccination. Additionally, the attitudes and beliefs that mothers reported as reasons for not having the influenza vaccination during pregnancy are also subject to recall bias.

The influenza vaccine receipt variable lumped together those who received either the H1N1 influenza vaccine (given during the 2009-2010 influenza season in addition to the seasonal influenza vaccine) or the seasonal influenza vaccine during pregnancy, since the question asked about influenza vaccines in general. It is possible that there was

heterogeneity in the uptake of childhood vaccination by type of maternal influenza vaccine, but that information was not available for analysis here, particularly as mothers in one year may have received both, neither, or only one of the H1N1 influenza vaccine and the seasonal influenza vaccine. Heterogeneity may be explored in future research, particularly as efforts to increase influenza vaccination have differed based on the severity of seasonal influenza and whether or not it is widespread in a given region.

The inactivated influenza vaccine may be given at any point during pregnancy (Centers for Disease Control and Prevention, 2013d). Additionally, while some studies on influenza vaccination during pregnancy have excluded women whose due dates fall in certain months, the present study did not restrict analyses based on due date. The influenza season varies by year, with outbreaks occurring as early as October and with activity occurring as late as May (Centers for Disease Control and Prevention, 2014b), and it is unlikely that any given pregnancy would not include a portion of one or even two influenza seasons.

The assumption of homogeneity between responders and non-responders inherent in the use of survey weights is also a limitation. This is nearly a ubiquitous issue in survey research, though since MN PRAMS has some demographic information on the non-responders, they are able to create survey weights that take into account some characteristics of those who did not respond. While unweighted analyses were conducted and were not qualitatively different from the weighted analyses, it is important to note that it is possible that responders are different than non-responders and weighting itself may amplify these differences in some subgroups since using the weights imputes data for the non-responders and those not sampled.

Another limitation is a problem of multiple comparisons. Though there are only five hypotheses of interest, this study reports the results of statistical tests on a variety of covariates and the results of chi-squared tests and post-estimation risk differences for the primary outcomes. Using a Bonferroni method of correcting for multiple comparisons was rejected as it can artificially inflate confidence intervals (Greenland & Rothman, 2008) and increase the type II error rate among non-null findings (Rothman, 1990), which is undesirable in an exploratory study. Focusing on statistical significance, particularly in the exploratory aim of this study, may be misguided. An examination of the confidence intervals, the magnitude of the point estimates, and the question of whether or not a risk difference of a certain magnitude is important for the outcome itself may be more informative than relying solely on significance. Nevertheless, it is important to note that a greater understanding of these relationships will be developed as high quality research of maternal behaviors and beliefs as predictors of early childhood vaccination continues. Science advances as more research and replications are conducted. The results of any one study, including the present, must be interpreted with caution and in the context of the current research about these health behaviors.

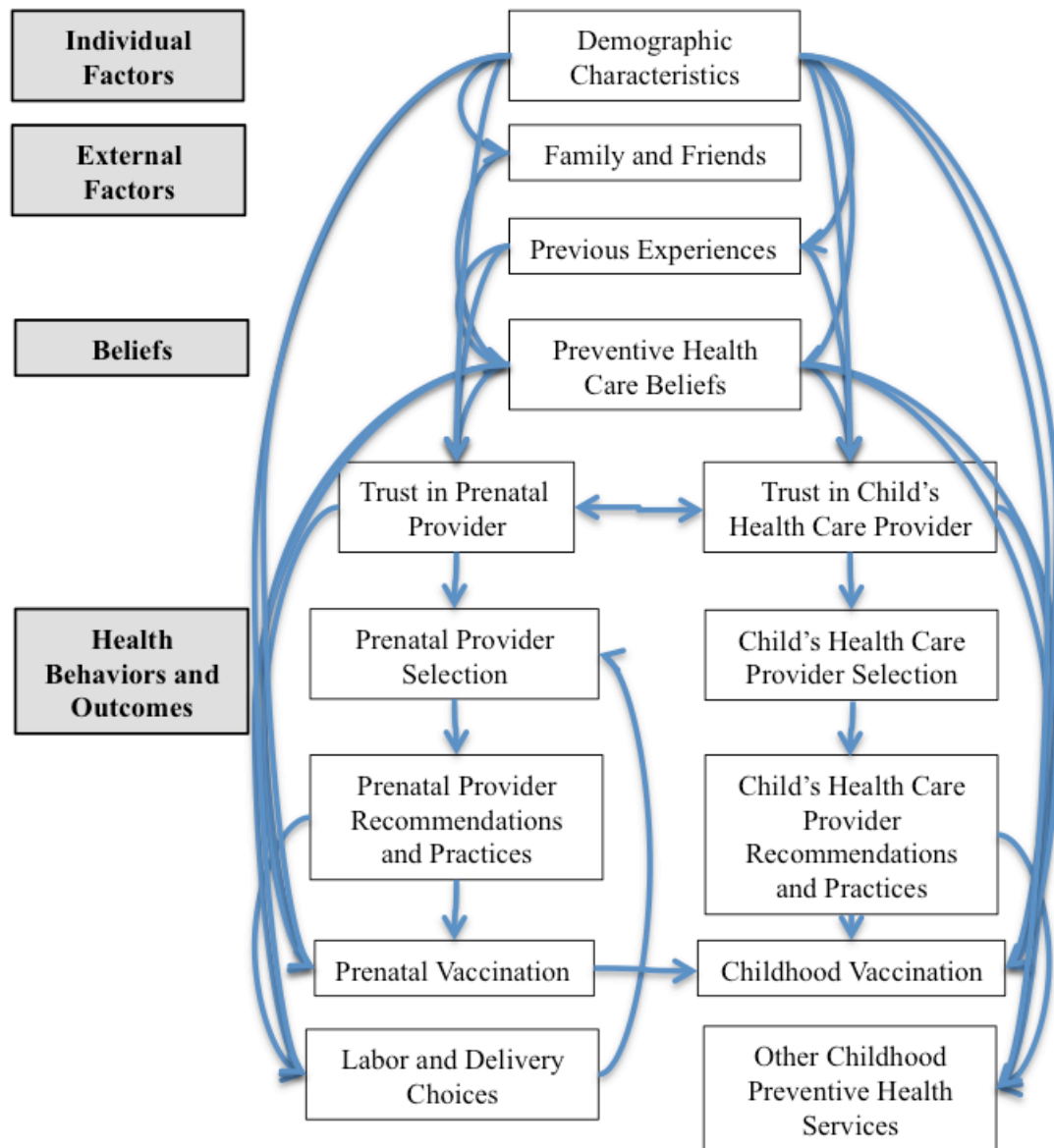
Future research may involve the use of study design (including subject selection) or statistical methods that increase the exchangeability between exposure groups in order to identify causal mechanisms. Adjustment in regression models is merely an attempt to achieve conditional exchangeability, ideally achieved with randomization in the study design, but nonetheless often the tool of choice for researchers, particularly when conducting analyses of existing data.

Exchangeability may be a particularly important consideration in studies of women who choose to deliver in OOH settings. It is well known that some subgroups of women have much higher rates of planned OOH births than others (Declercq et al., 2010). If certain subgroups of women do not choose to have OOH births, that is, they do not have a positive probability of exposure or there are no overlaps between subgroups, statements of causal effects among those subgroups cannot be made (Rubin, 1997). While randomly assigning birthing place would likely be unethical, a careful examination of the factors that predict OOH births is warranted in order to ensure exchangeable exposure groups when OOH birth is considered an exposure in analyses, especially when there are extreme sample size limitations among those with one exposure, as is the case here.

### *Implications*

This study demonstrates a relationship between maternal behaviors and beliefs and early childhood vaccination. There are several implications of these results. The identification of distal factors may help in identifying those at risk of not vaccinating their children. Additionally, if maternal behaviors exhibited prenatally are related to early childhood vaccine uptake, there is an opportunity for targeted prenatal interventions. More research must be done to confirm these results, including the further investigation of these distal maternal factors, specifically in identifying whether or not there may be an underlying belief system or provider practices influencing these and other beliefs and behaviors. If a larger belief system is identified, the compartmentalization of vaccination interventions without addressing the larger system may be misguided. A conceptual model outlining a potential framework for future research is presented in **Figure 1**.

**Figure 1. Preliminary Conceptual Model for Future Research into Maternal and Child Preventive Health Care.**



While the investigation of relationships between preventive health care components presented in this study was novel, it is important to consider a potential framework for the understanding of these relationships as research moves forward. In

**Figure 1**, the complex relationships between demographic factors, personal beliefs, and preventive health behaviors are preliminarily organized into a framework that could inform future research. As previously stated, it is unlikely that associations between the predictors and outcomes of interest in this study are causally related. What is more likely is that an underlying belief system, informed by previous experiences and other factors, along with provider recommendations are influencing preventive health choices. Future researchers may consider surveying parents about a broad range of preventive health behaviors and beliefs in order to understand whether or not there are identifiable groups of parents who are hesitant or skeptical about a variety of preventive health services.

Since this study is observational, that is to say it is without exposure randomization, and without a clear conceptual framework for why the exposures would impact the outcomes directly, precautions must be taken in the interpretation of the results. Instead of randomization leading to treatment assignment, observational studies require that we consider the “treatment selection mechanism” (Morgan & Winship, 2007, p. 41). In this study, this mechanism is unknown. Whether or not it is important to identify the causal mechanism depends on the health outcome of interest and the timing of potential interventions. While identifying that maternal health behaviors predict future child vaccination does not necessarily advance the understanding of a causal mechanism, it may be of practical importance for the timing and delivery of child vaccination interventions to subgroups of mothers or providers. The act of obtaining an influenza vaccination during pregnancy, for example, may be considered a surrogate marker for the underlying belief system and other factors that led these mothers to that health behavior. In demonstrating associations between these maternal and child health behaviors, though,

we may be closer to identifying a *common* treatment selection mechanism itself (perhaps the preventive health belief system as indicated in **Figure 1**) as applied to maternal health behaviors and childhood vaccination. Interventions aimed at the currently unknown and upstream treatment selection mechanism itself may have the potential to impact the uptake of a variety of preventive health services.

In this study, the difference in vaccine series and individual vaccine completion in children of mothers who had the influenza vaccine during pregnancy and children of mothers who did not is striking. There are no currently established values for clinically important differences for measures of vaccine uptake, but the risk differences identified in this study may be important for community immunity in a given population and, here, is the difference between being above or below national goals. Identifying these distal maternal factors as predictors of early childhood vaccination may be important in developing a more comprehensive understanding of vaccine refusal and delay. If the results of the present study are confirmed in other populations, interventions addressing both maternal influenza vaccination during pregnancy and childhood vaccination may be considered, particularly since previous interventions have found little to no effect on child vaccination rates (Kaufman et al., 2013; Sadaf et al., 2013).

Recently, an outbreak of measles in California (Centers for Disease Control and Prevention, 2015e) occurred in a population where there is very low compliance with the MMR vaccine schedule. This outbreak led to the spread of measles to multiple other states particularly due to exposure at a theme park and low vaccination compliance (Zipprich et al., 2015). High vaccination coverage is imperative to avoid the spread of vaccine-preventable illnesses, like measles, in venues with large numbers of visitors, both

domestic and international. Vaccination coverage is also important, though, in curbing the spread of vaccine-preventable illnesses in smaller venues. If those who refuse prenatal influenza vaccination or deliver in OOH settings share health care providers or have other similar lifestyles so that their children congregate, there could be the potential for an outbreak if a large proportion of their children are unvaccinated.

In infectious disease epidemiology, we study how infectious agents such as viruses and bacteria spread through the population. In social epidemiology, we study how ideas and behaviors can spread through the population in a manner similar to infectious diseases themselves. The spread of vaccine-hesitant beliefs can be detrimental if these beliefs influence behaviors and result in decreases in community immunity. This is especially important if decreased community immunity leads to the increased spread of infectious diseases themselves, since the spread of infectious diseases depends primarily on human interactions. The study of these beliefs and behaviors in a social context, including the investigation of potential differences by demographic factors or region or the identification of clusters, can lead to the prevention of negative health outcomes.

As previous models have shown, opinion clustering is important, as is the clustering of the children themselves (Eames, 2009). Consideration of clustering is important when vaccination itself depends on a large percentage of the population being vaccinated. Vaccination as protection for the general population also relies upon the assumption of randomly distributed vaccination, but if there is clustering this necessarily means there is nonrandom vaccination and these populations may not meet thresholds for community immunity (Fine et al., 2011). Future research may also focus on geographical trends, such as clustering of these children as they prepare to enter school, commonalities



in providers, or common community activities. Some research has examined vaccine exemptions for school-aged children, but, since this vaccine schedule is recommended to occur prior to 19 months of age and many of the deleterious effects of these vaccine-preventable illnesses occur in younger children, school exemptions may be a later outcome than would be desirable.

As research moves forward, investigating provider effects on both prenatal influenza vaccine uptake and early childhood vaccine uptake may be considered. It is possible that some providers are more likely to recommend prenatal influenza vaccines and/or that some providers are more likely to deliver literature about early childhood vaccines prenatally to their patients. It may be especially important to observe the recommendations as they occur in the office rather than rely on maternal recall. Previous research has shown that provider recommendation of childhood vaccines is important even for those with vaccine-hesitant views (Smith, Kennedy, Wooten, Gust, & Pickering, 2006), though this research has not been replicated with regard to prenatal providers. Studying whether or not there are differences in vaccination recommendations between providers who attend hospital births compared to OOH births may also be important. A consideration of whether or not mothers choose prenatal providers based upon provider vaccination views or recommendations may also be important. Social trends may be influencing provider practices and recommendations just as providers influence patient choices.

As research moves forward, other prenatal preventive health services should be considered as potential predictors of child vaccine uptake. In addition to the influenza vaccine, Tdap vaccination is also recommended for pregnant women. Current estimates

of the uptake of the Tdap vaccine during pregnancy vary widely, from 14.3% to 81.6% in two recent studies (Goldfarb, Little, Brown, & Riley, 2014; Housey et al., 2014), though research investigating the uptake of Tdap during pregnancy is in its infancy, particularly since the recommendation for Tdap during *each* pregnancy is relatively recent (American College of Obstetricians and Gynecologists, 2013). One study showed that influenza vaccine receipt during pregnancy was an independent predictor of Tdap uptake (Goldfarb et al., 2014). Another study found that women who were unvaccinated for influenza and pertussis were aware of the risks of influenza and pertussis, but still remained reluctant to have prenatal vaccinations (Chamberlain et al., 2015). The relationship between Tdap vaccination during pregnancy and child vaccination may be investigated, as well, particularly since the goal of Tdap vaccination during pregnancy is to effectively “cocoon” the infant before he/she is able to be vaccinated (American College of Obstetricians and Gynecologists, 2013; Murphy et al., 2008). Mothers and other family members themselves frequently spread pertussis to infants before they can be vaccinated (Bisgard et al., 2004; Wendelboe et al., 2007). Unfortunately, pertussis can be very severe in infants under one year of age, often resulting in complications and hospitalization (Centers for Disease Control and Prevention, 2013c). Other household members of infants or those expected to be in contacts with infants are also encouraged to get the Tdap vaccine (Centers for Disease Control and Prevention, 2011). Investigating the relationships between both prenatal Tdap and influenza vaccination and childhood vaccination might allow us to piece together the larger picture of preventive health uptake.

Another important intersection of social epidemiology and infectious disease epidemiology is that an underlying belief system of general preventive-health skepticism

must be considered. Social trends in the uptake of other preventive health services may be associated with child vaccination. As the research moves forward in investigating maternal behaviors as predictors of early childhood vaccination, prenatal Tdap vaccination must be considered since it is a relatively new recommendation and little is known about its relationship with other preventive health care behaviors. In addition, other preventive health care for young children, such as vitamin K injections and fluoride varnish, may also be considered as a potential underlying belief system is investigated since they have previously been linked to differences in vaccine uptake (Cassell et al., 2006; Chi, 2014). Utilization of CAM providers has been shown to be associated with decreased vaccination (Benin et al., 2006; Gaudino & Robison, 2012) and may be considered in future research of a potential underlying belief system.

Skepticism about vaccines has typically been researched in a vacuum. That is, there are bodies of literature reporting on parental beliefs about childhood vaccines, in general and separately, and a body of literature reporting on maternal beliefs about vaccines during pregnancy. Few studies have investigated maternal and childhood vaccination together and those that do focus on the HPV vaccine, less relevant to the current study and early childhood vaccination, since vaccination for HPV is shrouded in parental concern about morality. Tying together research on these important preventive health topics and prenatal decision-making could advance the understanding of parental decision-making regarding vaccines and why current interventions have had little effect on vaccination outcomes. Whether there is a larger belief system underlying these decisions or whether there is a structural problem, such as differential recommendation

by care providers serving these families, causing these mothers and children to fall through the cracks is unknown.

Increasing the understanding of the uptake of and beliefs about maternal and childhood preventive health components in general could lead to the development of interventions that target each of the components. This is particularly important since many parents do not recall getting any information about vaccination during pregnancy (Wu et al., 2008), despite wanting information about childhood vaccination prior to their children's first expected vaccinations (Vannice et al., 2011). It is possible that there is a missed opportunity during pregnancy for the provision of information regarding preventive health care for children during early childhood. While prenatal providers and pediatricians are obvious potential partners for intervention delivery, a variety of other trusted caregivers, such as doulas and community health workers, may also be investigated as important components of the preventive health care system as it relates to maternal and child vaccination.

Replicating this study, perhaps in another PRAMS-participating state that also has a high coverage registry, could help confirm a relationship between maternal influenza vaccination and child vaccination beyond Minnesota. If the relationship between prenatal influenza vaccination and childhood vaccination persist in other populations, there could be important practice implications and new directions for future research. Interventionists designing and implementing efforts to increase influenza vaccine uptake during pregnancy may consider testing components designed to increase early childhood vaccination. Interventions delivered to or through physicians, nurses, and midwives who

provide prenatal care may also be tested for their effectiveness in increasing the uptake of both prenatal influenza vaccination and childhood vaccinations.

Despite the public health perspective that vaccination is integral to community health, it is also important to acknowledge that parents want to make healthy choices for their children and those who choose not to vaccinate their children may have come to a different conclusion about what they believe is healthy for their children. Investigating parents' previous experiences with health care providers and attitudes about the health care system and medicine in general, as well as the use of CAM providers, may be important next steps. Additionally, the vaccine-related beliefs and behaviors of the partners of these mothers (if applicable) or the children's other parent(s) (if applicable) were not investigated here, but it may be essential to understand whether or not there are discordant vaccine-related or preventive health-related beliefs or behaviors within households or families.

In summary, this study contributes evidence that maternal behaviors and beliefs occurring prenatally may be predictors of early childhood vaccination. Childhood vaccination is not likely to be directly influenced by the act of obtaining an influenza vaccination during pregnancy or giving birth in a certain location. What is more likely is that there is an underlying system of beliefs or underlying circumstances influencing each of these behaviors and, perhaps, other preventive health behaviors. The body of literature on child vaccination has often focused on identifying proximal factors that predict vaccine uptake, but the results of this study show promise for the identification of distal predictors and further opportunities for research and intervention. Future research should focus on early identification, perhaps in the prenatal period, of those less likely to

vaccinate their children. Earlier identification of those at risk of not vaccinating their children may be key in developing effective interventions for increasing the uptake of childhood vaccinations.

## **Human Subjects**

This study has been deemed exempt by the Minnesota Department of Health Institutional Review Board (project #14-332) as of March 27, 2014. This study was re-reviewed and deemed exempt as of February 27, 2015, valid through March 27, 2016.

There will be no physical, emotional, economic, cultural, or social risks due to this research. The principal investigator will not have access to identifying information as MDH will de-identify the dataset prior to transferring the data to the principal investigator. Appropriate data confidentiality protocols will be followed prior to de-identification. MDH is responsible for the data safety of any paper surveys collected, which are maintained on MDH premises and will not be accessed for the purposes of this study. The principal investigator will store de-identified data on a password-protected computer. The data will be removed from the machine once all analyses are completed or the contract end date has passed, whichever comes first. Subjects will not be individually identifiable in any reports or articles that result from this study. These data protection procedures are likely to be highly effective in minimizing any risk to participants. Subjects will be notified per MDH protocols in the event of a security breach.

There will be no direct benefits to the subjects. There may be benefits to future children who are born to mothers who can be identified as being at higher risk of not vaccinating their children if mothers can be identified as “at risk” of choosing not to vaccinate. There is the potential for the identification of mothers who may choose not to vaccinate their children and allow for targeted interventions to be designed that adequately address the barriers to vaccination for these mothers and children. The long-term societal benefits of increased vaccination would be the potential for lower incidence

of vaccine-preventable illnesses due to lower numbers of susceptible individuals in the population and sustained or increased herd immunity, protecting those who are unable to be vaccinated.

The principal investigator has training in human subjects protection through Collaborative Institutional Training Initiative (CITI) Training (University of Miami, n.d.). The most recent trainings were the following:

- 1) CITI Social and Behavioral Responsible Conduct of Research (Passed 04/03/15)
- 2) Social/Behavioral or Humanist Research Investigators or Key Personnel – Refresher Course (Passed 04/03/15)
- 3) CITI Health Information Privacy and Security (HIPS) for Students and Instructors, Basic Course (Passed 01/15/13)
- 4) Social & Behavioral Research - Basic/Refresher, Basic Course (Passed 01/16/13)

MN PRAMS data is classified under Minnesota Statute 144.053 (Office of the Revisor of Statutes - State of Minnesota, 2014a), public health research by the state, while MIIC data is classified under Minnesota Statute 144.3351 (Office of the Revisor of Statutes - State of Minnesota, 2014b). Mothers responding to MN PRAMS have consented to having their responses used for research purposes. MIIC is an opt-out registry and data may be used according to the Immunization Data Sharing Law, MN Statute 144.3351 (Office of the Revisor of Statutes - State of Minnesota, 2014b).

Since the original data collection has taken place and there will be no direct participant involvement, no additional safeguards will be implemented for the purpose of



this secondary data analysis. Standard data confidentiality protocols will be implemented as defined previously.

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## Appendix A: MN PRAMS Survey

### PRAMS Survey Phase 6

Please mark your answers. Follow the directions included with the questions. If no directions are presented, check the box next to your answer or fill in the blanks. Because not all questions will apply to everyone, you may be asked to skip certain questions.

#### BEFORE PREGNANCY

First, we would like to ask a few questions about *you* and the time *before* you got pregnant with your new baby.

**1. At any time during the 12 months before you got pregnant with your new baby, did you do any of the following things?**

For each item, circle Y (Yes) if you did it or circle N (No) if you did not.

- a. I was dieting (changing my eating habits) to lose weight. N/Y
- b. I was exercising 3 or more days of the week. N/Y
- c. I was regularly taking prescription medicines other than birth control. N/Y
- d. I visited a health care worker to be checked or treated for diabetes. N/Y
- e. I visited a health care worker to be checked or treated for high blood pressure. N/Y
- f. I visited a health care worker to be checked or treated for depression or anxiety. N/Y
- g. I talked to a health care worker about my family medical history. N/Y
- h. I had my teeth cleaned by a dentist or dental hygienist. N/Y

**2. During the *month* before you got pregnant with your new baby, were you covered by any of these health insurance plans?**

Check all that apply.

- Health insurance from your job or the job of your husband, partner, or parents.
- Health insurance that you or someone else paid for (not from a job).
- Medicaid or Medical Assistance
- TRICARE or other military health care
- Indian Health Service or Tribal Health Service
- MinnesotaCare
- Minnesota Family Planning Program
- Other sources, please tell us:
- I did not have any health insurance before I got pregnant

**3. During the *month before* you got pregnant with your new baby, how many times a week did you take a multivitamin, a prenatal vitamin, or a folic acid vitamin?**

- I didn't take a multivitamin, prenatal vitamin, or folic acid vitamin at all
- 1 to 3 times a week
- 4 to 6 times a week
- Every day of the week

**4. *Just before* you got pregnant with your new baby, how much did you weigh?**

Pounds:            **OR**            Kilos:

**5. How tall are you without shoes?**

Feet:            Inches:            **OR**            Meters:

**6. What is your date of birth?**

Month:            Day:            Year:

**7. Would you say that, in general, your health is:**

- Excellent
- Very good
- Good
- Fair
- Poor

**8. *Before* you got pregnant with your new baby, did a doctor, nurse, or other health care worker talk with you about how to prepare for a healthy pregnancy and baby?**

N/Y

**9. *Before* you got pregnant with your new baby, were you ever told by a doctor, nurse, or other health care worker that you had Type 1 or Type 2 diabetes?**

This is not the same as gestational diabetes or diabetes that starts during pregnancy.

N/Y



**10. During the 3 months before you got pregnant with your new baby, did you have any of the following health problems?**

For each one, circle Y (Yes) if you had the problem or circle N (No) if you did not.

- |                                      |     |
|--------------------------------------|-----|
| a. Asthma                            | N/Y |
| b. High blood pressure (Hypertension | N/Y |
| c. Anemia (poor blood, low iron)     | N/Y |
| d. Heart problems                    | N/Y |
| e. Epilepsy (seizures)               | N/Y |
| f. Thyroid problems                  | N/Y |
| g. Depression                        | N/Y |
| h. Anxiety                           | N/Y |

**11. Before you got pregnant with your new baby, did you ever have any other babies who were born alive?**

No: Go to Question 14  
Yes: Go to Question 12

**12. Did the baby born *just before* your new one weigh more than 5 pounds, 8 ounces (2.5 kilos) at birth?**

No Yes

**13. Was the baby *just before* your new one born *more* than 3 weeks before his or her due date?**

No Yes

The next questions are about the time when you got pregnant with your *new* baby.

**14. Thinking back to *just before* you got pregnant with your *new* baby, how did you feel about becoming pregnant?**

Check one answer.

- I wanted to be pregnant sooner
- I wanted to be pregnant later
- I wanted to be pregnant then
- I didn't want to be pregnant then or at any time in the future

**15. When you got pregnant with your new baby, were you trying to get pregnant?**

No Go to Question 16  
Yes Go to Question 18

**16. When you got pregnant with your new baby, were you or your husband or partner doing anything to keep from getting pregnant?**

Some things people do to keep from getting pregnant include not having sex at certain times (natural family planning or rhythm) or withdrawal, and using birth control methods, such as the pill, condoms, vaginal ring, IUD, having their tubes tied, or their partner having a vasectomy.

No                      Go to Question 17  
Yes                     Go to Question 18

**17. What were your reasons or your husband's or partner's reasons for not doing anything to keep from getting pregnant?**

Check all that apply.

- I didn't mind if I got pregnant
- I thought I could not get pregnant at that time
- I had side effects from the birth control method I was using
- I had problems getting birth control when I needed it
- I thought my husband or partner or I was sterile (could not get pregnant at all)
- My husband or partner didn't want to use anything
- Other:                Please tell us

## **DURING PREGNANCY**

The next questions are about the prenatal care you received during your most recent pregnancy. Prenatal care includes visits to a doctor, nurse, or other health care worker before your baby was born to get checkups and advice about pregnancy. (It may help to look at the calendar when you answer these questions.)

**18. How many weeks or months pregnant were you when you were sure you were pregnant?**

For example, you had a pregnancy test or a doctor or nurse said you were pregnant.

Weeks                **OR**                Months                **OR**                I don't remember

**19. How many weeks or months pregnant were you when you had your first visit for prenatal care?**

Do not count a visit that was only for a pregnancy test or only for WIC (the Special Supplemental Nutrition Program for Women, Infants, and Children).

Weeks                **OR**                Months:                Go to Question 20

I don't remember:                                      Go to Question 21



**20. Did you get prenatal care as early in your pregnancy as you wanted?**

- |     |                   |
|-----|-------------------|
| No  | Go to Question 21 |
| Yes | Go to Question 22 |

**21. Did any of these things keep you from getting prenatal care at all or as early as you wanted?**

For each item, circle T (True) if it was a reason that you didn't get prenatal care when you wanted or circle F (False) if it was not a reason for you or if something does not apply to you.

- a. I couldn't get an appointment when I wanted one. T/F
- b. I didn't have enough money or insurance to pay for my visits. T/F
- c. I had no transportation to get to the clinic or doctor's office. T/F
- d. The doctor or my health plan would not start care as early as I wanted. T/F
- e. I had too many other things going on. T/F
- f. I couldn't take time off from work or school. T/F
- g. I didn't have my Medicaid, Medical Assistance, or MinnesotaCare card. T/F
- h. I had no one to take care of my children. T/F
- i. I didn't know that I was pregnant. T/F
- j. I didn't want anyone else to know I was pregnant. T/F
- k. I didn't want prenatal care. T/F

If you did not go for prenatal care, go to Question 24.

**22. Did any of the health insurance plans help you pay for your *prenatal care*?**

Check all that apply.

- Health insurance from your job or the job of your husband, partner, or parents.
- Health insurance that you or someone else paid for (not from a job).
- Medicaid or Medical Assistance
- TRICARE or other military health care
- Indian Health Service or Tribal Health Service
- MinnesotaCare
- Other sources, please tell us:
- I did not have any health insurance to help pay for my prenatal care

**23. During any of your prenatal care visits, did a doctor, nurse, or other health care worker talk with you about any of the things listed below?**

*Please count only discussions, not reading materials or videos.* For each item, circle Y (Yes) if someone talked with you about it or circle N (No) if no one talked with you about it.

- a. How smoking during pregnancy could affect my baby. N/Y
- b. Breastfeeding my baby. N/Y

- c. How drinking alcohol during pregnancy could affect my baby. N/Y
- d. Using a seat belt during my pregnancy. N/Y
- e. Medicines that are safe to take during my pregnancy. N/Y
- f. How using illegal drugs could affect my baby. N/Y
- g. Doing tests to screen for birth defects or diseases that run in my family. N/Y
- h. The signs and symptoms of preterm labor (labor more than 3 weeks before the baby is due). N/Y
- i. What to do if my labor starts early. N/Y
- j. Getting tested for HIV (the virus that causes AIDS). N/Y
- k. What to do if I feel depressed during my pregnancy or after my baby is born. N/Y
- l. Physical abuse to women by their husbands or partners. N/Y
- m. Birth control methods to use after my pregnancy. N/Y
- n. Mercury levels in fish and safe eating guidelines to protect me and my baby. N/Y

**24. At any time during *your most recent* pregnancy or delivery, did you have a test for HIV (the virus that causes AIDS)?**

No                      Yes                      I don't know

**25. Did you get a flu vaccination during *your most recent* pregnancy?**

No                      Yes

**26. During *your most recent* pregnancy, were you on WIC (the Special Supplemental Nutrition Program for Women, Infants, and Children)?**

No                      Yes

**27. During *your most recent* pregnancy, were you told by a doctor, nurse, or other health care worker that you had gestational diabetes (diabetes that started during *this* pregnancy)?**

No                      Yes

**28. Did you have any of the following problems during *your most recent* pregnancy?**

For each item, circle Y (Yes) if you had the problem or circle N (No) if you did not.

- a. Vaginal bleeding. N/Y
- b. Kidney or bladder (urinary tract infection). N/Y
- c. Severe nausea, vomiting, or dehydration. N/Y
- d. Cervix had to be sewn shut (cerclage for incompetent cervix). N/Y
- e. High blood pressure, hypertension (including pregnancy-induced hypertension [PIH]), preeclampsia, or toxemia. N/Y
- f. Problems with the placenta (such as abruptio placentae or placenta previa). N/Y
- g. Labor pains more than 3 weeks before my baby was due (preterm or early labor). N/Y



- h. Water broke more than 3 weeks before my baby was due (premature rupture of membranes [PROM]). N/Y
- i. I had to have a blood transfusion. N/Y
- j. I was hurt in a car accident. N/Y

The next questions are about smoking cigarettes around the time of pregnancy (before, during, and after).

**29. Have you smoked any cigarettes in the *past 2 years*?**

- |     |                   |
|-----|-------------------|
| No  | Go to Question 33 |
| Yes | Go to Question 30 |

**30. In the *3 months before* you got pregnant, how many cigarettes did you smoke on an average day?**

A pack has 20 cigarettes.

- 41 cigarettes or more
- 21 to 40 cigarettes
- 11 to 20 cigarettes
- 6 to 10 cigarettes
- 1 to 5 cigarettes
- Less than 1 cigarette
- I didn't smoke then

**31. In the *last 3 months* of your pregnancy, how many cigarettes did you smoke on an average day?**

A pack has 20 cigarettes.

- 41 cigarettes or more
- 21 to 40 cigarettes
- 11 to 20 cigarettes
- 6 to 10 cigarettes
- 1 to 5 cigarettes
- Less than 1 cigarette
- I didn't smoke then

**32. How many cigarettes do you smoke on an average day *now*?**

A pack has 20 cigarettes.

- 41 cigarettes or more
- 21 to 40 cigarettes

- 11 to 20 cigarettes
- 6 to 10 cigarettes
- 1 to 5 cigarettes
- Less than 1 cigarette
- I didn't smoke then

**33. Which of the following statements best describes the rules about smoking *inside your home now*?**

Check one answer.

- No one is allowed to smoke anywhere inside my home.
- Smoking is allowed in some rooms or at some times.
- Smoking is permitted anywhere inside my home.

**34. Have you had any alcoholic drinks in the *past 2 years*?**

A drink is 1 glass of wine, wine cooler, can or bottle of beer, shot of liquor, or mixed drink.

No	Go to Question 37
Yes	Go to Question 35a

**35a. During the *3 months before you got pregnant*, how many alcoholic drinks did you have in an average week?**

- 14 drinks or more a week
- 7 to 13 drinks a week
- 4 to 6 drinks a week
- 1 to 3 drinks a week
- Less than 1 drink a week
- I didn't drink then: Go to Question 36a

**35b. During the *3 months before you got pregnant*, how many times did you drink 4 alcoholic drinks or more in one sitting?**

A sitting is a two hour time span.

- 6 or more times
- 4 to 5 times
- 2 to 3 times
- 1 time
- I didn't have 4 drinks or more in 1 sitting

**36a. During the last 3 months of your pregnancy, how many alcoholic drinks did you have in an average week?**

- 14 drinks or more a week
- 7 to 13 drinks a week
- 4 to 6 drinks a week
- 1 to 3 drinks a week
- Less than 1 drink a week
- I didn't drink then: Go to Questions 37

**36b. During the last 3 months of your pregnancy, how many times did you drink 4 alcoholic drinks or more in one sitting?**

A sitting is a two hour time span.

- 6 or more times
- 4 to 5 times
- 2 to 3 times
- 1 time
- I didn't have 4 drinks or more in 1 sitting

Pregnancy can be a difficult time for some women. The next questions are about things that may have happened before and during your most recent pregnancy.

**37. This question is about things that may have happened during the 12 months before your new baby was born.**

For each item, circle Y (Yes) if it happened to you or circle N (No) if it did not. (It may help to look at the calendar when you answer these questions.)

- a. A close family member was very sick and had to go into the hospital. N/Y
- b. I got separated or divorced from my husband or partner. N/Y
- c. I moved to a new address. N/Y
- d. I was homeless. N/Y
- e. My husband or partner lost his job. N/Y
- f. I lost my job even though I wanted to go on working. N/Y
- g. I argued with my husband or partner more than usual. N/Y
- h. My husband or partner said he didn't want me to be pregnant. N/Y
- i. I had a lot of bills I couldn't pay. N/Y
- j. I was in a physical fight. N/Y
- k. My husband or partner or I went to jail. N/Y
- l. Someone very close to me had a problem with drinking or drugs. N/Y
- m. Someone very close to me died. N/Y



**38. During the 12 months before your new baby was born, did you ever eat less than you felt you should because there wasn't enough money to buy food?**

No Yes

**39. During the 12 months before you got pregnant with your new baby, did your husband or partner push, hit, slap, kick, choke, or physically hurt you in any other way?**

No Yes

**40. During your most recent pregnancy, did your husband or partner push, hit, slap, kick, choke, or physically hurt you in any other way?**

No Yes

The next questions are about your labor and delivery. (It may help to look at the calendar when you answer these questions).

**41. When was your baby due?**

Month Day Year

**42. When did you go into the hospital to have your baby?**

Month Day Year

**43. When was your baby born?**

Month Day Year

**44. When were you discharged from the hospital after your baby was born?**

Month Day Year

**45. Did any of these health insurance plans help you pay for the delivery of your new baby?**

Check all that apply.

- Health insurance from your job or the job of your husband, partner, or parents
- Health insurance that you or someone else paid for (not from a job)
- Medicaid or Medical Assistance
- TRICARE or other military health care
- Indian Health Service or Tribal Health Service
- MinnesotaCare



- Other sources, please tell us:
- I did not have any health insurance to help pay for my delivery

## **AFTER PREGNANCY**

The next questions are about the time since your new baby was born.

**46. After your baby was born, was he or she put in an intensive care unit?**

No                      Yes                      I don't know

**47. After your baby was born, how long did he or she stay in the hospital?**

- Less than 24 hours (less than 1 day)
- 24 to 48 hours (1 to 2 days)
- 3 to 5 days
- 6 to 14 days
- More than 14 days
- My baby was not born in a hospital
- My baby is still in the hospital: Go to Question 50

**48. Is your baby alive now?**

No:                      Go to Question 60  
Yes:                      Go to Question 49

**49. Is your baby living with you now?**

No:                      Go to Question 60  
Yes:                      Go to Question 50

**50. Did you ever breastfeed or pump breast milk to feed your new baby after delivery, even for a short period of time?**

No:                      Go to Question 55b  
Yes:                      Go to Question 51

**51. Are you currently breastfeeding or feeding pumped milk to your new baby?**

No:                      Go to Question 52  
Yes:                      Go to Question 54

**52. How many weeks or months did you breastfeed or pump milk to feed your baby?**

Weeks

Months

Less than 1 week

**53. What were your reasons for stopping breastfeeding?**

Check all that apply.

- My baby had difficulty latching or nursing
- Breast milk alone did not satisfy my baby
- I thought my baby was not gaining enough weight
- My nipples were sore, cracked, or bleeding
- It was too hard, painful, or too time consuming
- I thought I was not producing enough milk
- I had too many other household duties
- I felt it was the right time to stop breastfeeding
- I got sick and was not able to breastfeed
- I went back to work or school
- My baby was jaundiced (yellowing of the skin or whites of the eyes)
- Other:            Please tell us

If your baby was not born in a hospital, go to Question 55a.

**54. This question asks about things that may have happened at the hospital where your new baby was born.**

For each item, circle Y (Yes) if it happened or circle N (No) if it did not happen.

- a. Hospital staff gave me information about breastfeeding. N/Y
- b. My baby stayed in the same room with me at the hospital. N/Y
- c. I breastfed my baby in the hospital. N/Y
- d. I breastfed in the first hour after my baby was born. N/Y
- e. Hospital staff helped me learn how to breastfeed. N/Y
- f. My baby was fed only breast milk at the hospital. N/Y
- g. Hospital staff told me to breastfeed whenever my baby wanted. N/Y
- h. The hospital gave me a breast pump to use. N/Y
- i. The hospital gave me a gift pack with formula. N/Y
- j. The hospital gave me a telephone number to call for help with breastfeeding. N/Y
- k. My baby used a pacifier in the hospital. N/Y

**55a. How old was your new baby the first time he or she drank liquids other than breast milk (such as formula, water, juice, tea, or cow's milk)?**

Weeks                      OR                      Months

**55b. How old was your new baby the first time he or she ate food (such as baby cereal, baby food, or any other food)?**

- # of Weeks
- # of Months
- My baby was less than 1 week old
- My baby has not eaten any foods

If your baby is still in the hospital, go to Question 60.

**56. In which *one* position do you most often lay your baby down to sleep now?**

Check one answer.

- On his or her side
- On his or her back
- On his or her stomach

**57. How often does your new baby sleep in the same bed with you or anyone else?**

- Always
- Often
- Sometimes
- Rarely
- Never

**58. Was your new baby seen by a doctor, nurse, or other health care worker for a *one week check-up* after he or she was born?**

No                      Yes

**59. Has your new baby had a well-baby checkup?**

A well-baby checkup is a regular health visit for your baby usually at 1, 2, 4, and 6 months of age.

No                      Yes



**60. Are you or your husband or partner doing anything *now* to keep from getting pregnant?**

Some things people do to keep from getting pregnant include not having sex at certain times (natural family planning or rhythm) or withdrawal, and using birth control methods, such as the pill, condoms, vaginal ring, IUD, having their tubes tied, or their partner having a vasectomy.

- |     |                   |
|-----|-------------------|
| No  | Go to Question 61 |
| Yes | Go to Question 62 |

**61. What are your reasons or your husband's or partner's reasons for not doing anything to keep from getting pregnant *now*?**

Check all that apply.

- I am not having sex
- I want to get pregnant
- I don't want to use birth control
- My husband or partner doesn't want to use anything
- I don't think I can get pregnant (sterile)
- I can't pay for birth control
- I am pregnant now
- Other:            Please tell us:

**62. *Since your new baby was born*, have you had a postpartum checkup for yourself?**

A postpartum checkup is the regular checkup a woman has about 6 weeks after she gives birth.

- |    |     |
|----|-----|
| No | Yes |
|----|-----|

**63. Below is a list of feelings and experience that women sometimes have after childbirth. Read each item to determine how well it describes your feelings and experiences. Then, write on the line the number of the choice that best describes how often you have felt or experienced things this way since your new baby was born. Use the scale when answering:**

1. Never      2. Rarely      3. Sometimes      4. Often      5. Always

- a. I felt down, depressed, or sad
- b. I felt hopeless
- c. I felt slowed down

## OTHER EXPERIENCES

The next questions are on a variety of topics.

**64. How would you describe the time during your *most recent* pregnancy?**

Check one answer.

- One of the happiest times of my life
- A happy time with few problems
- A moderately hard time
- A very hard time
- One of the worst times of my life

**65. This question is about the care of your teeth during your *most recent* pregnancy.**

For each item, circle Y (Yes) if it is true or circle N (No) if it is not true.

- a. I needed to see a dentist for a problem. N/Y
- b. I went to a dentist or dental clinic. N/Y
- c. A dental or other health care worker talked with me about how to care for my teeth and gums. N/Y

**66. During your *most recent* pregnancy, did you get any of these services?**

For each one, circle Y (Yes) if you got the service or circle N (No) if you did not get it.

**67. Are you currently in school or working outside the home?**

- No, I don't work or go to school
- No, I'm on maternity leave, but plan to return to work
- Yes

If your baby is not alive or is not living with you, go to Question 71.

**68. Have you ever heard or read about what can happen if a baby is shaken?**

No                      Yes

**69. Since your new baby was born, have you used any of these services?**

For each one, circle Y (Yes) if you used the service or circle N (No) if you did not use it.

- a. Parenting classes. N/Y
- b. Visits to your home by a nurse or other health care worker. N/Y
- c. Counseling for depression or anxiety. N/Y

**70. Since your new baby was born, did any doctor, nurse, or other health care worker talk with you about any of the things listed below?**

*Please count only discussions*, not reading materials or videos. For each item, circle Y (Yes) if someone talked with you about it or circle N (No) if no one talked with you about it.

- a. Help with or information about breastfeeding. N/Y
- b. How long to wait before getting pregnant. Again. N/Y
- c. Birth control methods that I can use after giving birth. N/Y
- d. Postpartum depression. N/Y
- e. Support groups for new parents. N/Y
- f. Resources in my community such as nurse home visitation programs, telephone hotlines, counseling, etc. N/Y
- g. Getting to and staying at a healthy weight after delivery. N/Y

**71. Since you delivered your new baby, who would help you if a problem came up?**

For example, who would help you if you needed to borrow \$50 or if you got sick and had to be in bed for several weeks?

Check all that apply.

- My husband or partner
- My mother, father, or in-laws
- Other family member or relative
- A friend
- Religious community
- Someone else - please tell us who:
- No one would help

**72. Since you delivered your new baby, have you been tested for diabetes or high blood sugar?**

No                      Yes

The last questions are about the time during the 12 months before your new baby was born.



**73. During the 12 months before your new baby was born, what was your yearly total household income before taxes?**

Include your income, your husband's or partner's income, and any other income you may have received. All information will be kept private and will not affect any services you are now getting.

- Less than \$10,000
- \$10,000 to \$14,999
- \$15,000 to \$19,999
- \$20,000 to \$24, 999
- \$25,000 to \$34,999
- \$35,000 to \$49,999
- \$50,000 or more

**74. During the 12 months before your new baby was born, how many people, *including yourself*, depended on this income?**

# of people

**75. What is today's date?**

Month                  Day                  Year

Please use this space for any additional comments you would like to make about the health of mothers and babies in Minnesota.

Thanks for answering our questions!  
Your answers will help us work to make Minnesota mothers and babies healthier.

## Appendix B: MN PRAMS Seasonal Influenza Vaccination Questions

These next questions are about the flu shot.

**F1. At anytime during your most recent pregnancy, did a doctor, nurse, or other health care worker offer you a flu shot or tell you to get one?**

- ☐ No  
☐ Yes

**F2. Since August 1, 2010, did you get a flu shot?**

- ☐ No → **Go to Question F6**  
☐ Yes ↓

**F3. Did you get this flu shot *during* or *after* your most recent pregnancy?**

- ☐ During my pregnancy  
☐ After I delivered my baby

**F4. During what month and year did you get the flu shot?**

- ☐ August 2010  
☐ September 2010  
☐ October 2010  
☐ November 2010  
☐ December 2010  
☐ January 2011  
☐ February 2011  
☐ March 2011  
☐ April 2011  
☐ May 2011  
☐ June 2011

☐ I don't remember

**F5. Where did you get your flu shot?**

Check one answer

- ☐ My obstetrician or gynecologist's office  
☐ My family doctor or other doctor's office  
☐ A health department or community clinic  
☐ A hospital  
☐ A pharmacy, drug store or grocery store  
☐ My work place or school  
☐ Other → Please tell us:

**If you got a flu shot, go to Question F7.**

**F6. What were your reasons for not getting a flu shot since August 1, 2010?** For each reason, check **No** if it was not a reason for you, or check **Yes** if it was.

**No Yes**

- a. My doctor didn't mention anything about getting a flu shot..... N Y  
b. I was worried about side effects of the flu shot for me..... N Y  
c. I was worried that the flu shot might harm my baby..... N Y  
d. I was not worried about getting sick with the flu..... N Y  
e. I do not think the flu shot works..... N Y  
f. I don't normally get a flu shot..... N Y  
g. Other reason..... N Y  
Please tell us:



**The last questions are about flu illness.**

**F7. At any time during *your most recent* pregnancy, were you sick with a fever?**

- ☐ No
- ☐ Yes

**F8. At any time during *your most recent* pregnancy, did a doctor, nurse or other health care worker tell you that you had the flu?**

- ☐ No
  - ☐ Yes
- **Survey complete**
- ↓

**F9. Were you hospitalized for the flu during *your most recent* pregnancy?**

- ☐ No
- ☐ Yes

**Thank you for answering these final questions! Your answers will help us learn how to keep pregnant women healthy.**